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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.

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## FEDERAL LABOR RELATIONS AUTHORITY

## 5 CFR Part 2418

## New Debt-Collection Regulations

**AGENCY:** Federal Labor Relations Authority.

**ACTION:** Final rule.

**SUMMARY:** Pursuant to the Debt Collection Improvement Act of 1996, the Federal Labor Relations Authority (''FLRA'') is issuing a regulation governing procedures for collecting debts owed to the federal government by present and former FLRA employees. The regulation sets forth the procedures that the FLRA will follow in collecting debts owed to the United States arising from activities under FLRA jurisdiction. These procedures include collection of debts through administrative offset and salary offset. These regulations supersede the FLRA's debt-collection procedures applied under FLRA Internal Regulation 2790, dated December 29, 1986.

**DATES:** Effective May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Gina Grippando, Counsel for Regulatory and Public Affairs, Federal Labor Relations Authority, Washington, DC 20424, (202) 218–7776.

**SUPPLEMENTARY INFORMATION:**

### Background

This final rule implements the Debt Collection Improvement Act of 1996 (DCIA). The DCIA requires federal agencies to collect debts owed to the United States under regulations prescribed by the head of the agency, and standards prescribed by the Department of Justice and the Department of the Treasury. 31 U.S.C. 3711(d)(2). These standards, known as the Federal Claims Collection Standards (FCCS), became effective on December 22, 2000. 31 CFR chapter IX, parts 900 through 904.

The DCIA also requires agencies, prior to collecting debts owed to the United States, to: (1) Adopt, without change, regulations on collecting debts by offset promulgated by the Department of Justice or Department of the Treasury (FCCS); or (2) prescribe agency regulations for collecting such debts by offset, which are consistent with the FCCS. 31 U.S.C. 3716. Agency regulations protect the minimum due-process rights that must be afforded to the debtor when an agency seeks to collect a debt by administrative offset, including the ability to verify, challenge, and compromise claims, and access to administrative-appeals procedures which are both reasonable and protect the interests of the United States. Nothing in this regulation precludes the use of collection remedies not contained in this regulation.

The final rule is consistent with the FCCS, as required by the DCIA. The salary-offset portion of the rule has been submitted to and approved by the Office of Personnel Management (OPM), as required by 5 U.S.C. 5514(b)(1).

### Section Analysis of the Final Rule

*A. Subpart A—General Provisions, Definitions, Scope, Applicability*

Subpart A of the final rule sets out the definitions, scope, and applicability of the FLRA's debt-collection procedures. The final rule provides procedures for the collection of FLRA debts as well as procedures for collection of other debts owed to the United States when the FLRA receives, from another agency, a request for offset of an FLRA payment. The FLRA shall follow the procedural standards for collecting debts set forth in the FCCS when it determines that it is appropriate to initiate debt collection or seek offset to collect a debt. 31 CFR parts 900 through 904. The rule does not apply to tax debts or to any debt for which there is an indication of fraud or misrepresentation, as described in § 900.3 of the FCCS. Additionally, the final rule does not preclude the FLRA from collecting debts under statutes and regulations other than those described in the final rule.

*B. Subpart B—Procedures To Collect FLRA Debts*

Subpart B of the final rule provides the procedures that the FLRA will use to collect debts. Among other things, subpart B outlines the due-process procedures that the FLRA is required to follow when using offset (administrative, tax refund, and salary) to collect a debt, when garnishing a debtor's wages, or before reporting a debt to a credit bureau. More specifically, the final rule describes the notice that the FLRA will send to a debtor when collecting the debt, including the FLRA's responsibilities and the debtor's associated rights and obligations related to the notice. The FLRA shall assess interest, penalties, and administrative costs on such debts in accordance with the provisions of 31 U.S.C. 3717 and 31 CFR 901.9. Subpart B also explains that the FLRA may waive those assessments, and it provides for situations in which the FLRA may accept payments in regular installments, in accordance with 31 CFR 901.8. The subpart also provides that the FLRA may suspend or terminate a debt and when it will transfer an FLRA debt to the Treasury Department's Financial Management Service for collection under 31 U.S.C. 3711(g) and 31 CFR 285.12. This subpart provides that an employee may request a waiver of the debt, if applicable, and references Appendix A of the final rule, which describes ''Waiving Claims Against FLRA Employees for Erroneous Payments.''

*C. Subpart C—Procedures for Offset of FLRA Payments To Collect Debts Owed to Other Federal Agencies*

Subpart C of the final rule authorizes the FLRA to collect debts owed to other federal agencies, and it describes the procedures to be followed when another agency would like to use the offset process to collect a debt from a nontax payment issued by the FLRA, as a payment agency. For example, any federal agency may request that the FLRA collect a debt owed to such agency by offsetting funds payable to a debtor by the FLRA, including salary payments issued to FLRA employees. This subpart describes where to send a request and provides that certification of the debt is required. Subpart C also describes what the FLRA will do upon receipt of a request to offset the salary of an FLRA employee, including, among other things, the notice given to the employee and the limits on the amount

that the FLRA will deduct from an employee's salary.

**Administrative Procedure Act—Regulatory Analysis**

The FLRA has determined that this rule pertains to agency practice and procedure and is interpretative in nature. The procedures contained in the rule for salary offset and administrative offset are mandated by law and by regulations promulgated by OPM, jointly by the Department of the Treasury and the Department of Justice, and by the IRS. Notice of proposed rulemaking is not required under the Administrative Procedure Act (APA) because the rule pertains solely to agency procedure and practice. 5 U.S.C. 553(b)(3)(A). Notice and an opportunity for public comment are not necessary prior to issuance of this final rule because it implements a definitive statutory scheme mandated by the DCIA. Likewise, pursuant to 5 U.S.C. 553(d)(3), the agency finds that good cause exists for not providing a delayed effective date.

*Regulatory Flexibility Act*

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Moreover, the rule will affect only persons who owe delinquent nontax debts to the Treasury Department and other federal agencies. Accordingly, a regulatory-flexibility analysis is not required.

*Paperwork Reduction Act*

The final rule is not subject to the Paperwork Reduction Act (44 U.S.C. 3501), since it does not contain any new information-collection requirements.

*E.O. 12866, Regulatory Review*

This rule is not a significant regulatory action as defined in Executive Order 12866. Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act do not apply.

**List of Subjects in 5 CFR Part 2418**

Administrative practice and procedure, Claims, Debts, Garnishment of wages, Government employees, Hearing procedures, Pay administration, Salaries, Wages.

By the Federal Labor Relations Authority on April 24, 2015.

**Carol Waller Pope,**

*Chairman.*

**Authority and Issuance**

For the reasons set forth in the preamble, the FLRA adds 5 CFR part 2418 to read as follows:

## PART 2418—FLRA DEBT COLLECTION

### Subpart A—General Provisions

Sec.
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**Appendix A To Part 2418—Waiving Claims Against Flra Employees For Erroneous Payments**

**Authority:** 5 U.S.C. 5514; 5 U.S.C. 5584; 5 U.S.C. 6402; 31 U.S.C. 3701, 3711; 3716, 3717, 3718, 3720A, 3720D.

### Subpart A—General Provisions

#### § 2418.1 What definitions apply to the regulations in this part?

As used in this part:

*Administrative offset* or *offset* means withholding funds payable by the United States (including funds payable by the United States on behalf of a State Government) to, or held by the United States for, a person to satisfy a debt owed by the person. The term ''administrative offset'' includes, but is not limited to, the offset of Federal salary, vendor, retirement, and Social-Security-benefit payments. The terms ''centralized administrative offset'' and ''centralized offset'' refer to the process by which the Treasury Department's Financial Management Service offsets Federal payments through the Treasury Offset Program.

*Administrative wage garnishment* means the process by which a Federal agency orders a non-Federal employer to withhold amounts from a debtor's wages to satisfy a debt, as authorized by 31 U.S.C. 3720D, 31 CFR 285.11, and this part.

*Agency* or *federal agency* means a department, agency, court, court administrative office, or instrumentality in the executive, judicial, or legislative branch of the Federal Government, including government corporations.

*Chairman* means the Chairman of the FLRA or his or her designee.

*Creditor agency* means any Federal agency that is owed a debt.

*Debt* means any amount of money, funds, or property that has been determined by an appropriate official of the Federal Government to be owed to the United States by a person. As used in this part, the term ''debt'' does not include, as described in 31 U.S.C. 3701(d), debts arising under: The Internal Revenue Code of 1986 (26 U.S.C. 1 *et seq.*); the Social Security Act (42 U.S.C. 301 *et seq.*), except to the extent provided under sections 204(f) and 1631(b)(4) of such Act [42 U.S.C. 404(f) and 1383(b)(4)] and section 3716(c) [31 U.S.C. 3716(c)], or the tariff laws of the United States.

*Debtor* means a person who owes a debt to the United States.

*Delinquent debt* means a debt that has not been paid by the date specified in the agency's initial written demand for payment or applicable agreement or instrument (including a post-delinquency payment agreement) unless other satisfactory payment arrangements have been made.

*Delinquent FLRA debt* means a delinquent debt owed to the FLRA.

*Disposable pay* has the same meaning as that term is defined in 5 CFR 550.1103.

*Employee* or *Federal employee* means a current employee of the FLRA or other Federal agency, including a current member of the Armed Forces, Reserve of the Armed Forces of the United States, or the National Guard.

*Executive Director* means the Executive Director of the FLRA or his or her designee.

*FCCS* means the Federal Claims Collection Standards, which were jointly published by the Departments of the Treasury and Justice and codified at 31 CFR parts 900 through 904.

*Financial Management Service* means the Financial Management Service, a bureau of the Treasury Department, which is responsible for the centralized collection of delinquent debts through the offset of Federal payments and other means.

*FLRA* means the Federal Labor Relations Authority and all of its components.

*FLRA debt* means a debt that a person owes the FLRA.

*Payment agency* or *Federal payment agency* means any Federal agency that transmits payment requests in the form of certified payment vouchers, or other similar forms, to a disbursing official for disbursement. The ''payment agency'' may be the agency that employs the debtor. In some cases, the FLRA may be both the creditor agency and the payment agency.

*Person* means an individual, corporation, partnership, association, organization, State or local government, or any other type of entity other than a Federal agency.

*Salary offset* means a type of administrative offset to collect, from the current pay account of a Federal employee, a debt that the employee owes.

*Tax refund offset* is defined in 31 CFR 285.2(a).

*Treasury Department* means the United States Department of the Treasury. *Waiver* means the cancellation, remission, forgiveness, or non-recovery of a debt allegedly owed by an employee to an agency as permitted or required by 5 U.S.C. 5584, 10 U.S.C. 2774, 32 U.S.C. 716, 5 U.S.C. 8346(b), 42 U.S.C. 404(b), or any other law.

### § 2418.2 Why is the FLRA issuing these regulations, and what do they cover?

(a) *Scope.* This part provides procedures for the collection of FLRA debts. This part also provides procedures for collection of other debts owed to the United States when the FLRA receives, from another agency, a request for offset of an FLRA payment (for example, when an FLRA employee owes a debt to the United States Department of Education).

(b) *Applicability.* (1) This part applies to the FLRA when collecting an FLRA debt, to persons who owe FLRA debts, and to Federal agencies requesting offset of a payment issued by the FLRA as a payment agency (including salary payments to FLRA employees).

(2) This part does not apply to tax debts or to any debt for which there is an indication of fraud or misrepresentation, as described in 31 CFR 900.3 of the FCCS, unless the Department of Justice returns the debt to the FLRA for handling.

(3) Nothing in this part precludes collection or disposition of any debt under statutes and regulations other than those described in this part. See, for example, 5 U.S.C. 5705, Advancements and Deductions, which authorizes agencies to recover travel advances by offset of up to 100% of a Federal employee's accrued pay. See, also, 5 U.S.C. 4108, governing the collection of training expenses. To the extent that the provisions of laws and other regulations differ from the provisions of this part, those provisions of law and other regulations—and not the provisions of this part—apply to the remission or mitigation of fines, penalties, and forfeitures, as well as debts arising under the tariff laws of the United States.

(c) *Duplication not required.* Nothing in this part requires the FLRA to duplicate notices or administrative proceedings required by contract, this part, or other laws or regulations.

(d) *Use of multiple collection remedies allowed.* The FLRA and other Federal agencies may simultaneously use multiple collection remedies to collect a debt, except as prohibited by law. This part is intended to promote aggressive debt collection, using for each debt all available collection remedies. These remedies are not listed in any prescribed order, so that the FLRA may have flexibility in determining which remedies will be most efficient in collecting the particular debt.

### § 2418.3 Do these regulations adopt the Federal Claims Collection Standards (FCCS)?

This part adopts and incorporates all provisions of the FCCS. This part also supplements the FCCS by prescribing procedures consistent with the FCCS, as necessary and appropriate for FLRA operations.

## Subpart B—Procedures to Collect FLRA Debts

### § 2418.4 What notice will the FLRA send to a debtor when collecting an FLRA debt?

(a) *Notice requirements.* The FLRA shall aggressively collect FLRA debts. The FLRA shall promptly send at least one written notice to a debtor informing the debtor of the consequences of failing to pay or otherwise resolve an FLRA debt. The notice(s) shall be sent to the debtor at the most current address of the debtor in the FLRA's records. Generally, before starting the collection actions described in §§ 2418.5 and 2418.9 through 2418.16, the FLRA will send no more than two written notices to the debtor. The purpose of the notice(s) is to explain why the debt is owed, the amount of the debt, how a debtor may pay the debt or make alternative payment arrangements, how a debtor may review documents related to the debt, how a debtor may dispute the debt, the collection remedies available to the FLRA if the debtor refuses to pay the debt, and other consequences to the debtor if the debt is not paid. Except as otherwise provided in paragraph (b) of this section, the written notice(s) shall explain to the debtor:

(1) The nature and amount of the debt, and the facts giving rise to the debt;

(2) How interest, penalties, and administrative costs are added to the debt, the date by which payment should be made to avoid such charges, and that such assessments must be made unless excused in accordance with 31 CFR 901.9 (see § 2418.5);

(3) The date by which payment should be made to avoid the enforced collection actions described in paragraph (a)(6) of this section;

(4) The FLRA's willingness to discuss alternative payment arrangements and how the debtor may enter into a written agreement to repay the debt under terms acceptable to the FLRA (see § 2418.6);

(5) The name, address, and telephone number of a contact person or office within the FLRA;

(6) The FLRA's intention to enforce collection if the debtor fails to pay or otherwise resolve the debt, by taking one or more of the following actions:

(i) *Offset.* Offset the debtor's Federal payments, including income-tax

refunds, salary, certain benefit payments (such as Social Security), retirement, vendor, travel reimbursements and advances, and other Federal payments (see §§ 2418.10 through 2418.12);

(ii) *Private collection agency.* Refer the debt to a private collection agency (see § 2418.15);

(iii) *Credit-bureau reporting.* Report the debt to a credit bureau (see § 2418.14);

(iv) *Administrative wage garnishment.* Garnish the debtor's wages through administrative wage garnishment (see § 2418.13);

(v) *Litigation.* Refer the debt to the Department of Justice to initiate litigation to collect the debt (see § 2418.16);

(vi) *Treasury Department's Financial Management Service.* Refer the debt to the Financial Management Service for collection (see § 2418.9);

(7) That Treasury debts over 180 days delinquent must be referred to the Financial Management Service for the collection actions described in paragraph (a)(6) of this section (see § 2418.9);

(8) How the debtor may inspect and copy records related to the debt;

(9) How the debtor may request a review of the FLRA's determination that the debtor owes a debt and present evidence that the debt is not delinquent or legally enforceable (see §§ 2418.10(c) and 2418.11(c));

(10) How a debtor may request a hearing if the FLRA intends to garnish the debtor's private-sector (*i.e.,* non-Federal) wages (see § 2418.13(a)), including:

(i) The method and time period for requesting a hearing;

(ii) That the timely filing of a request for a hearing on or before the 15th business day following the date of the notice will stay the commencement of administrative wage garnishment, but not necessarily other collection procedures; and

(iii) The name and address of the office to which the request for a hearing should be sent.

(11) How a debtor who is a Federal employee subject to Federal salary offset may request a hearing (see § 2418.12(e)), including:

(i) The method and time period for requesting a hearing;

(ii) That the timely filing of a request for a hearing on or before the 15th calendar day following receipt of the notice will stay the commencement of salary offset, but not necessarily other collection procedures;

(iii) The name and address of the office to which the request for a hearing should be sent;

(iv) That the FLRA will refer the debt to the debtor's employing agency or to the Financial Management Service to implement salary offset, unless the employee files a timely request for a hearing;

(v) That a final decision on the hearing, if requested, will be issued at the earliest practical date, but not later than 60 days after the filing of the request for a hearing, unless the employee requests and the hearing official grants a delay in the proceedings;

(vi) That any knowingly false or frivolous statements, representations, or evidence may subject the Federal employee to penalties under the False Claims Act (31 U.S.C. 3729–3731) or other applicable statutory authority, and criminal penalties under 18 U.S.C. 286, 287, 1001, and 1002, or other applicable statutory authority;

(vii) That, unless prohibited by contract or statute, amounts paid on or deducted for the debt that are later waived or found not owed to the United States will be promptly refunded to the employee; and

(viii) That 5 U.S.C. 5514 and 31 U.S.C. 3716 govern proceedings with respect to such debt.

(12) How the debtor may request a waiver of the debt, if applicable (see Appendix A of this part);

(13) How the debtor's spouse may claim his or her share of a joint-income-tax refund by filing Form 8379 with the Internal Revenue Service (see *http://www.irs.gov*);

(14) How the debtor may exercise other statutory or regulatory rights and remedies available to the debtor;

(15) That an employee's involuntary payment of all or any portion of a debt being collected will not be construed as a waiver of any rights that the employee may have under any provision of contract or law, unless there are statutory, regulatory, or contractual provisions to the contrary; and

(16) That the debtor should advise the FLRA of a bankruptcy proceeding of the debtor or another person liable for the debt being collected.

(b) *Exceptions to notice requirements.* The FLRA may omit from a notice to a debtor one or more of the provisions contained in paragraphs (a)(6) through (16) of this section if the FLRA, in consultation with its legal counsel, determines that any provision is not legally required given the collection remedies to be applied to a particular debt.

(c) *Respond to debtors; comply with FCCS.* The FLRA will respond promptly to communications from debtors and comply with other FCCS provisions applicable to the administrative collection of debts. See 31 CFR part 901.

**§ 2418.5 How will the FLRA add interest, penalty charges, and administrative costs to an FLRA debt?**

(a) *Assessment and notice.* The FLRA shall assess interest, penalties, and administrative costs on FLRA debts in accordance with the provisions of 31 U.S.C. 3717 and 31 CFR 901.9. Interest shall be charged in accordance with the requirements of 31 U.S.C. 3717(a). Penalties shall accrue at the rate of 6% per year, or such other higher rate as authorized by law. The FLRA shall determine administrative costs, that is, the costs of processing and handling a delinquent debt. In the notice to the debtor described in § 2418.4, the FLRA must explain how interest, penalties, costs, and other charges are assessed, unless the requirements are included in a contract or repayment agreement.

(b) *Waiver of interest, penalties, and administrative costs.* Unless otherwise required by law, the FLRA may not charge interest if the amount due on the debt is paid within 30 days after the date from which the interest accrues. See 31 U.S.C. 3717(d). The FLRA may waive interest, penalties, and administrative costs, or any portion thereof, when it would be against equity and good conscience or not in the FLRA's best interest to collect such charges, in accordance with FLRA guidelines for waiving claims against FLRA employees for erroneous overpayments. See appendix A of this part.

(c) *Accrual during suspension of debt collection.* In most cases, interest, penalties, and administrative costs will begin and continue to accrue 30 days after notice is given to the employee and during any period when collection has been suspended for any reason (for example, when the debtor has requested a hearing). The FLRA may suspend accrual of any or all of these charges when accrual would be against equity and good conscience or not in the FLRA's best interest, in accordance with FLRA guidelines for waiving claims against FLRA employees for erroneous overpayments. See appendix A of this part.

**§ 2418.6 When will the FLRA allow a debtor to pay an FLRA debt in installments instead of one lump sum?**

If a debtor is financially unable to pay the debt in one lump sum, then the FLRA may accept payment of an FLRA debt in regular installments, in accordance with 31 CFR 901.8.

**§ 2418.7 When will the FLRA compromise an FLRA debt?**

If the FLRA cannot collect the full amount of an FLRA debt, then the FLRA may compromise the debt in accordance with 31 CFR part 902.

**§ 2418.8 When will the FLRA suspend or terminate debt collection on an FLRA debt?**

If, after pursuing all appropriate means of collection, the FLRA determines that an FLRA debt is uncollectible, then the FLRA may suspend or terminate debt-collection activity in accordance with the provisions of 31 CFR part 903 and the FLRA's policies and procedures.

**§ 2418.9 When will the FLRA transfer an FLRA debt to the Treasury Department's Financial Management Service for collection?**

(a) The FLRA will transfer any eligible debt that is more than 180 days delinquent to the Financial Management Service for debt-collection services, a process known as ''cross-servicing.'' See 31 U.S.C. 3711(g) and 31 CFR 285.12. The FLRA may transfer debts delinquent 180 days or less to the Financial Management Service in accordance with the procedures described in 31 CFR 285.12. The Financial Management Service takes appropriate action to collect or compromise the transferred debt, or to suspend or terminate collection action thereon, in accordance with the statutory and regulatory requirements and authorities applicable to the debt and the collection action to be taken. See 31 CFR 285.12(c)(2). Appropriate action includes, but is not limited to: Contact with the debtor; referral of the debt to the Treasury Offset Program, private collection agencies, or the Department of Justice; reporting of the debt to credit bureaus; and administrative wage garnishment.

(b) At least sixty (60) days before transferring an FLRA debt to the Financial Management Service, the FLRA will send notice to the debtor as required by § 2418.4. The FLRA will certify to the Financial Management Service, in writing, that the debt is valid, delinquent, legally enforceable, and that there are no legal bars to collection. In addition, the FLRA will certify its compliance with all applicable due-process and other requirements as described in this part and other Federal laws. See 31 CFR 285.12(i) regarding the certification requirement.

(c) As part of its debt-collection process, the Financial Management Service uses the Treasury Offset Program to collect Treasury debts by administrative and tax-refund offset. See 31 CFR 285.12(g). The Treasury Offset Program is a centralized offset program administered by the Financial Management Service to collect delinquent debts owed to Federal agencies and states (including past-due child support). Under the Treasury Offset Program, before a Federal payment is disbursed, the Financial Management Service compares the name and taxpayer identification number (TIN) of the payee with the names and TINs of debtors that have been submitted by Federal agencies and states to the Treasury Offset Program database. If there is a match, the Financial Management Service (or, in some cases, another Federal disbursing agency) offsets all or a portion of the Federal payment, disburses any remaining payment to the payee, and pays the offset amount to the creditor agency. Federal payments eligible for offset include, but are not limited to, income-tax refunds, salary, travel advances and reimbursements, retirement and vendor payments, and Social Security and other benefit payments.

**§ 2418.10 How will the FLRA use administrative offset (offset of non-tax Federal payments) to collect an FLRA debt?**

(a) *Centralized administrative offset through the Treasury Offset Pro*gram. (1) In most cases, the Financial Management Service uses the Treasury Offset Program to collect Treasury debts by the offset of Federal payments. See § 2418.9(c). If not already transferred to the Financial Management Service under § 2418.9, the FLRA will refer any eligible debt over 180 days delinquent to the Treasury Offset Program for collection by centralized administrative offset. See 31 U.S.C. 3716(c)(6); 31 CFR part 285, subpart A; and 31 CFR 901.3(b). The FLRA may refer any eligible debt less than 180 days delinquent to the Treasury Offset Program for offset.

(2) At least sixty (60) days prior to referring a debt to the Treasury Offset Program, in accordance with paragraph (a)(1) of this section, the FLRA will send notice to the debtor in accordance with the requirements of § 2418.4. The FLRA will certify to the Financial Management Service, in writing, that the debt is valid, delinquent, legally enforceable, and that there are no legal bars to collection by offset. In addition, the FLRA will certify its compliance with the requirements described in this part.

(b) *Non-centralized administrative offset for FLRA debts.* (1) When centralized administrative offset through the Treasury Offset Program is not available or appropriate, the FLRA may collect past-due, legally enforceable FLRA debts through non-centralized administrative offset. See 31 CFR 901.3(c). In these cases, the FLRA may offset a payment internally or make an offset request directly to a Federal payment agency.

(2) At least thirty (30) days prior to offsetting a payment internally or requesting a Federal payment agency to offset a payment, the FLRA will send notice to the debtor in accordance with the requirements of § 2418.4. (For debts outstanding more than ten (10) years on or before June 11, 2009, the FLRA will comply with the additional notification requirements of 31 CFR 285.7(d).) When referring a debt for offset under this paragraph (b), the FLRA will certify, in writing, that the debt is valid, delinquent, legally enforceable, and that there are no legal bars to collection by offset. In addition, the FLRA will certify its compliance with these regulations concerning administrative offset. See 31 CFR 901.3(c)(2)(ii).

(c) *Administrative review.* The notice described in § 2418.4 shall explain to the debtor how to request an administrative review of the FLRA's determination that the debtor owes an FLRA debt and how to present evidence that the debt is not delinquent or legally enforceable. In addition to challenging the existence and amount of the debt, the debtor may seek a review of the terms of repayment. In most cases, the FLRA will provide the debtor with a ''paper hearing'' based upon a review of the written record, including documentation provided by the debtor. The FLRA shall provide the debtor with a reasonable opportunity for an oral hearing when the debtor requests reconsideration of the debt and the FLRA determines that the question of the indebtedness cannot be resolved by review of the documentary evidence, for example, when the validity of the debt turns on an issue of credibility or veracity. Unless otherwise required by law, an oral hearing under this section is not required to be a formal evidentiary hearing, although the FLRA will carefully document all significant matters discussed at the hearing. The FLRA may suspend collection through administrative offset and/or other collection actions pending the resolution of a debtor's dispute.

(d) *Procedures for expedited offset.* Under the circumstances described in 31 CFR 901.3(b)(4)(iii), the FLRA may effect an offset against a payment to be made to the debtor prior to sending a notice to the debtor, as described in § 2418.4, or completing the procedures

described in paragraph (b)(2) and (c) of this section. The FLRA shall give the debtor notice and an opportunity for review as soon as practicable and promptly refund any money ultimately found not to have been owed to the Government.

**§ 2418.11 How will the FLRA use tax-refund offset to collect an FLRA debt?**

(a) *Tax-refund offset.* In most cases, the Financial Management Service uses the Treasury Offset Program to collect FLRA debts by the offset of tax refunds and other Federal payments. See § 2418.9(c). If not already transferred to the Financial Management Service under § 2418.9, the FLRA will refer to the Treasury Offset Program any past-due, legally enforceable debt for collection by tax-refund offset. See 26 U.S.C. 6402(d), 31 U.S.C. 3720A and 31 CFR 285.2.

(b) *Notice.* At least sixty (60) days before referring a debt to the Treasury Offset Program, the FLRA will send notice to the debtor in accordance with the requirements of § 2418.4. The FLRA will certify to the Financial Management Service's Treasury Offset Program, in writing, that the debt is past due and legally enforceable in the amount submitted and that the FLRA has made reasonable efforts to obtain payment of the debt as described in 31 CFR 285.2(d). In addition, the FLRA will certify its compliance with all applicable due-process and other requirements described in this part and other Federal laws. See 31 U.S.C. 3720A(b) and 31 CFR 285.2.

(c) *Administrative review.* The notice described in § 2418.4 shall provide the debtor with at least 60 days prior to the initiation of tax-refund offset to request an administrative review as described in § 2418.10(c). The FLRA may suspend collection through tax-refund offset and/or other collection actions pending the resolution of the debtor's dispute.

**§ 2418.12 How will the FLRA offset a Federal employee's salary to collect an FLRA debt?**

(a) *Federal salary offset.* (1) Salary offset is used to collect debts that FLRA employees and other Federal employees owe to the United States. If a Federal employee owes an FLRA debt, then the FLRA may offset the employee's Federal salary to collect the debt in the manner described in this section. For information on how a Federal agency other than the FLRA may collect debt from the salary of an FLRA employee, see §§ 2418.19 and 2418.20.

(2) Nothing in this part requires the FLRA to collect an FLRA debt in accordance with this section if Federal law allows otherwise. See, for example, 5 U.S.C. 5705 (travel advances not used for allowable travel expenses are recoverable from the employee or his estate by setoff against accrued pay and other means) and 5 U.S.C. 4108 (recovery of training expenses).

(3) The FLRA may use the administrative-wage-garnishment procedure described in § 2418.13 to collect a debt from an individual's non-Federal wages.

(b) *Centralized salary offset through the Treasury Offset Program.* As described in § 2418.9(a), the FLRA will refer FLRA debts to the Financial Management Service for collection by administrative offset, including salary offset, through the Treasury Offset Program. When possible, the FLRA will attempt salary offset through the Treasury Offset Program before applying the procedures in paragraph (c) of this section. See 5 CFR 550.1109.

(c) *Non-centralized salary offset for FLRA debts.* When centralized salary offset through the Treasury Offset Program is not available or appropriate, the FLRA may collect delinquent FLRA debts through non-centralized salary offset. See 5 CFR 550.1109. In these cases, the FLRA may offset a payment internally or make a request directly to a Federal payment agency to offset a salary payment to collect a delinquent debt that a Federal employee owes. At least thirty (30) days prior to offsetting internally or requesting a Federal agency to offset a salary payment, the FLRA will send notice to the debtor in accordance with the requirements of § 2418.4. (For debts outstanding more than ten (10) years on or before June 11, 2009, the FLRA will comply with the additional notification requirements of 31 CFR 285.7(d).) When referring a debt for offset, the FLRA will certify to the payment agency, in writing, that the debt is valid, delinquent, and legally enforceable in the amount stated, and that there are no legal bars to collection by salary offset. In addition, the FLRA will certify that all due-process and other prerequisites to salary offset have been met. See 5 U.S.C. 5514, 31 U.S.C. 3716(a), and this section for a description of the due-process and other prerequisites for salary offset.

(d) *When prior notice not required.* The FLRA is not required to provide prior notice to an employee when the FLRA makes the following adjustments to an FLRA employee's pay:

(1) Any adjustment to pay arising out of any employee's election of coverage or a change in coverage under a Federal-benefits program requiring periodic deductions from pay, if the amount to be recovered was accumulated over four pay periods or less;

(2) A routine intra-agency adjustment of pay that is made to correct an overpayment of pay attributable to clerical or administrative errors or delays in processing pay documents, if the overpayment occurred within the four pay periods preceding the adjustment, and, at the time of such adjustment, or as soon thereafter as practical, the individual is provided written notice of the nature and the amount of the adjustment and the point of contact for contesting such adjustment; or

(3) Any adjustment to collect a debt amounting to $ 50 or less, if, at the time of such adjustment, or as soon thereafter as practical, the individual is provided written notice of the nature and the amount of the adjustment and a point of contact for contesting such adjustment.

(e) *Hearing procedures*—(1) *Request for a hearing.* A Federal employee who has received a notice that his or her FLRA debt will be collected by means of salary offset may request a hearing concerning the existence or amount of the debt. The Federal employee also may request a hearing concerning the amount proposed to be deducted from the employee's pay each pay period. The employee must send any request for hearing, in writing, to the office designated in the notice described in § 2418.4. See § 2418.4(a)(11). The request must be received by the designated office on or before the 15th calendar day following the employee's receipt of the notice. The employee must sign the request and specify whether an oral or paper hearing is requested. If an oral hearing is requested, then the employee must explain why the matter cannot be resolved by review of the documentary evidence alone. An oral hearing may, at the debtor's option, be conducted either in-person or by telephone conference. All travel expenses incurred by the Federal employee in connection with an in-person hearing will be borne by the employee. All telephonic charges incurred during the hearing will be the responsibility of the agency.

(2) *Failure to submit timely request for hearing.* If the employee fails to submit a request for hearing within the time period described in paragraph (e)(1) of this section, then the employee will have waived the right to a hearing, and salary offset may be initiated. However, the FLRA will accept a late request for hearing if the employee can show that the late request was the result of circumstances beyond the employee's control or because of a failure to receive actual notice of the filing deadline.

(3) *Hearing official.* The FLRA must obtain the services of a hearing official who is not under the supervision or control of the Chairman. The FLRA may contact an agent of any agency designated in appendix A to 5 CFR part 581 (List of Agents Designated to Accept Legal Process) to request a hearing official.

(4) *Notice of hearing.* After the employee requests a hearing, the designated hearing official shall inform the employee of the form of the hearing to be provided. For oral hearings, the notice shall set forth the date, time, and location of the hearing. For paper hearings, the notice shall notify the employee of the date by which he or she should submit written arguments to the designated hearing official. The hearing official shall give the employee reasonable time to submit documentation in support of the employee's position. The hearing official shall schedule a new hearing date if requested by both parties. The hearing official shall give both parties reasonable notice of the time and place of a rescheduled hearing.

(5) *Oral hearing.* The hearing official will conduct an oral hearing if he or she determines that the matter cannot be resolved by review of documentary evidence alone (for example, when an issue of credibility or veracity is involved). The hearing need not take the form of an evidentiary hearing, but may be conducted in a manner determined by the hearing official, including but not limited to:

(i) Informal conferences with the hearing official, in which the employee and agency representative will be given full opportunity to present evidence, witnesses, and argument;

(ii) Informal meetings with an interview of the employee by the hearing official; or

(iii) Formal written submissions, with an opportunity for oral presentation.

(6) *Paper hearing.* If the hearing official determines that an oral hearing is not necessary, then he or she will make the determination based upon a review of the available written record, including any documentation submitted by the employee in support of his or her position.

(7) *Failure to appear or submit documentary evidence.* In the absence of good cause shown (for example, excused illness), if the employee fails to appear at an oral hearing or fails to submit documentary evidence as required for a paper hearing, then the employee will have waived the right to a hearing, and salary offset shall be initiated. If the FLRA representative fails to appear at an oral hearing, then the hearing official shall proceed with the hearing as scheduled, and make his or her determination based upon the oral testimony presented and the documentary evidence submitted by both parties.

(8) *Burden of proof.* The FLRA will have the initial burden to prove the existence and amount of the debt. Thereafter, if the employee disputes the existence or amount of the debt, then the employee must prove by a preponderance of the evidence that no debt exists or that the amount of the debt is incorrect. In addition, the employee may present evidence that the proposed terms of the repayment schedule are unlawful, would cause a financial hardship to the employee, or that collection of the debt may not be pursued due to operation of law.

(9) *Record.* The hearing official shall maintain a summary record of any hearing provided by this part. Witnesses will testify under oath or affirmation in oral hearings.

(10) *Date of decision.* The hearing official shall issue a written opinion stating his or her decision, based upon documentary evidence and information developed at the hearing, as soon as practicable after the hearing, but not later than 60 days after the date on which the FLRA received the request for hearing. If the employee requests a delay in the proceedings, then the deadline for the decision may be postponed by the number of days by which the hearing was postponed. When a decision is not timely rendered, the FLRA shall waive penalties applied to the debt for the period beginning with the date the decision is due and ending on the date the decision is issued.

(11) *Content of decision.* The written decision shall include:

(i) A statement of the facts presented to support the origin, nature, and amount of the debt;

(ii) The hearing official's findings, analysis, and conclusions; and

(iii) The terms of any repayment schedules, if applicable.

(12) *Final agency action.* The hearing official's decision shall be final.

(f) *Waiver not precluded.* Nothing in this part precludes an employee from requesting waiver of an overpayment under 5 U.S.C. 5584 or 8346(b), 10 U.S.C. 2774, 32 U.S.C. 716, or other statutory authority.

(g) *Salary-offset process*—(1) *Determination of disposable pay.* The FLRA's Office of the Executive Director will determine the amount of an FLRA employee's disposable pay (as defined in § 2418.1) and will implement salary offset when requested to do so by the FLRA, as described in paragraph (c) of this section, or another agency, as described in § 2418.19. If the debtor is not employed by the FLRA, then the agency employing the debtor will determine the amount of the employee's disposable pay and will implement salary offset upon request.

(2) *When salary offset begins.* Deductions shall normally begin within three official pay periods following receipt of the creditor agency's request for offset.

(3) *Amount of salary offset.* The amount to be offset from each salary payment will be up to 15 percent of a debtor's disposable pay, as follows:

(i) If the amount of the debt is equal to or less than 15 percent of the disposable pay, then such debt generally will be collected in one lump-sum payment;

(ii) Installment deductions will be made over a period of no greater than the anticipated period of employment. An installment deduction will not exceed 15 percent of the disposable pay from which the deduction is made unless the employee has agreed in writing to the deduction of a greater amount, or a higher deduction has been ordered by a court under section 124 of Public Law 97–276 (96 Stat. 1195), or the creditor agency has determined that smaller deductions are appropriate based on the employee's ability to pay.

(4) *Final salary payment.* After the employee has separated either voluntarily or involuntarily from the payment agency, the payment agency may make a lump-sum deduction exceeding 15 percent of disposable pay from any final salary or other payments pursuant to 31 U.S.C. 3716 in order to satisfy a debt.

(h) *Payment agency's responsibilities.* (1) As required by 5 CFR 550.1109, if the employee separates from the payment agency from which the FLRA has requested salary offset, then the payment agency must certify the total amount of its collection and notify the FLRA and the employee of the amounts collected. If the payment agency is aware that the employee is entitled to payments from the Civil Service Retirement Fund and Disability Fund, the Federal Employee Retirement System, or other similar payments, then it must provide written notification to the payment agency responsible for making such payments that the debtor owes a debt, the amount of the debt, and that the FLRA has complied with the provisions of this section. The FLRA must submit a properly certified claim to the new payment agency before the collection can be made.

(2) If the employee is already separated from employment and all

payments due from his or her former payment agency have been made, then the FLRA may request that money due and payable to the employee from the Civil Service Retirement Fund and Disability Fund, the Federal Employee Retirement System, or other similar funds, be administratively offset to collect the debt. Generally, the FLRA will collect such monies through the Treasury Offset Program as described in § 2418.9(c).

(3) When an employee transfers to another agency, the FLRA should resume collection with the employee's new payment agency in order to continue salary offset.

**§ 2418.13 How will the FLRA use administrative wage garnishment to collect an FLRA debt from a debtor's wages?**

(a) The FLRA is authorized to collect debts from a debtor's wages by means of administrative wage garnishment in accordance with the requirements of 31 U.S.C. 3720D and 31 CFR 285.11. This part adopts and incorporates all of the provisions of 31 CFR 285.11 concerning administrative wage garnishment, including the hearing procedures described in 31 CFR 285.11(f). The FLRA may use administrative wage garnishment to collect a delinquent FLRA debt unless the debtor is making timely payments under an agreement to pay the debt in installments (see § 2418.6). At least thirty (30) days before initiating an administrative wage garnishment, the FLRA will send notice to the debtor in accordance with the requirements of § 2418.4 of this part, including the requirements of § 2418.4(a)(10). (For debts outstanding more than ten (10) years on or before June 11, 2009, the FLRA will comply with the additional notification requirements of 31 CFR 285.7(d).) For FLRA debts referred to the Financial Management Service under § 2418.9, the FLRA may authorize the Financial Management Service to send a notice informing the debtor that administrative wage garnishment will be initiated and how the debtor may request a hearing as described in § 2418.4(a)(10). If a debtor makes a timely request for a hearing, administrative wage garnishment will not begin until a hearing is held and a decision is sent to the debtor. See 31 CFR 285.11(f)(4). If a debtor's hearing request is not timely, then the FLRA may suspend collection by administrative wage garnishment in accordance with the provisions of 31 CFR 285.11(f)(5). All travel expenses incurred by the debtor in connection with an in-person hearing will be borne by the debtor. If a hearing is conducted telephonically, all telephonic charges incurred during the hearing will be the responsibility of the agency.

(b) This section does not apply to Federal salary offset, the process by which the FLRA collects debts from the salaries of Federal employees (see § 2418.12).

**§ 2418.14 How will the FLRA report FLRA debts to credit bureaus?**

The FLRA shall report delinquent FLRA debts to credit bureaus in accordance with 31 U.S.C. 3711(e), 31 CFR 901.4, and the Office of Management and Budget Circular A–129, ''Policies for Federal Credit Programs and Nontax Receivables.'' For additional information, see Financial Management Service's ''Guide to the Federal Credit Bureau Program,'' which may be found at *http://www.fms.treas.gov/debt.* At least sixty (60) days prior to reporting a delinquent debt to a consumer-reporting agency, the FLRA will send notice to the debtor in accordance with the requirements of § 2418.4. Before disclosing information to a consumer-reporting agency, the FLRA shall provide, on request of a person alleged to be responsible for the delinquent debt, for a review of the obligation of the debtor, including an opportunity for reconsideration of the initial decision on the debt. The FLRA may authorize the Financial Management Service to report to credit bureaus those delinquent FLRA debts that have been transferred to the Financial Management Service under § 2418.9.

**§ 2418.15 How will the FLRA refer FLRA debts to private collection agencies?**

The FLRA will transfer delinquent FLRA debts to the Financial Management Service to obtain debt-collection services provided by private collection agencies. See § 2418.9.

**§ 2418.16 When will the FLRA refer FLRA debts to the Department of Justice?**

(a) *Compromise or suspension or termination of collection activity.* The FLRA shall refer FLRA debts having a principal balance over $ 100,000, or such higher amount as authorized by the Attorney General, to the Department of Justice for approval of any compromise of a debt or suspension or termination of collection activity. See §§ 2418.7 and 2418.8; 31 CFR 902.1; 31 CFR 903.1.

(b) *Litigation.* The FLRA shall promptly refer to the Department of Justice for litigation delinquent FLRA debts on which aggressive collection activity has been taken in accordance with this part and that should not be compromised, and on which collection activity should not be suspended or terminated. See 31 CFR part 904. The FLRA may authorize the Financial Management Service to refer to the Department of Justice for litigation those delinquent FLRA debts that have been transferred to the Financial Management Service under § 2418.9.

**§ 2418.17 How does a debtor request a special review based on a change in circumstances such as catastrophic illness, divorce, death, or disability?**

(a) *Material change in circumstances.* A debtor who owes an FLRA debt may, at any time, request a special review by the FLRA of the amount of any offset, administrative wage garnishment, or voluntary payment, based on materially changed circumstances beyond the control of the debtor such as, but not limited to, catastrophic illness, divorce, death, or disability.

(b) *Inability to pay.* For purposes of this section, in determining whether an involuntary or voluntary payment would prevent the debtor from meeting essential subsistence expenses (costs incurred for food, housing, clothing, transportation, and medical care), the debtor shall submit a detailed statement and supporting documents for the debtor, his or her spouse, and dependents, indicating:

(1) Income from all sources;
(2) Assets;
(3) Liabilities;
(4) Number of dependents;
(5) Expenses for food, housing, clothing, and transportation;
(6) Child-care or elder-care expenses;
(7) Medical expenses; and
(8) Exceptional expenses, if any.

(c) *Alternative payment arrangement.* If the debtor requests a special review under this section, the debtor shall submit an alternative proposed payment schedule and a statement to the FLRA, with supporting documents, showing why the current offset, garnishment, or repayment schedule imposes an extreme financial hardship on the debtor. The FLRA will evaluate the statement and documentation and determine whether the current offset, garnishment, or repayment schedule imposes extreme financial hardship on the debtor. The FLRA shall notify the debtor in writing of such determination, including, if appropriate, a revised offset, garnishment, or payment schedule. If the special review results in a revised offset, garnishment, or repayment schedule, then the FLRA will notify the appropriate agency or other persons about the new terms.

**§ 2418.18 Will the FLRA issue a refund if money is erroneously collected on a debt?**

The FLRA shall promptly refund to a debtor any amount collected on an

FLRA debt when the debt is waived or otherwise found not to be owed to the United States, or as otherwise required by law. Refunds under this part shall not bear interest unless required by law.

## Subpart C—Procedures for Offset of FLRA Payments to Collect Debts Owed to Other Federal Agencies

### § 2418.19 How do other Federal agencies use the offset process to collect debts from payments issued by the FLRA?

(a) *Offset of FLRA payments to collect debts owed to other Federal agencies.* (1) In most cases, Federal agencies submit eligible debts to the Treasury Offset Program to collect delinquent debts from payments issued by the FLRA and other Federal agencies, a process known as ''centralized offset.'' When centralized offset is not available or appropriate, any Federal agency may ask the FLRA (when acting as a ''payment agency'') to collect a debt owed to such agency by offsetting funds payable to a debtor by the FLRA, including salary payments issued to FLRA employees. This section and § 2418.20 apply when a Federal agency asks the FLRA to offset a payment issued by the FLRA to a person who owes a debt to the United States.

(2) This subpart does not apply to FLRA debts. See §§ 2418.10 through 2418.12 for offset procedures applicable to FLRA debts.

(3) This subpart does not apply to the collection of non-FLRA debts through tax refund offset. See 31 CFR 285.2 for tax-refund-offset procedures.

(b) *Administrative offset (including salary offset); certification.* The FLRA will initiate a requested offset only upon receipt of written certification from the creditor agency that the debtor owes the past-due, legally enforceable debt in the amount stated, and that the creditor agency has fully complied with all applicable due-process and other requirements contained in 31 U.S.C. 3716, 5 U.S.C. 5514, and the creditor agency's regulations, as applicable. Offsets will continue until the debt is paid in full or otherwise resolved to the satisfaction of the creditor agency.

(c) *Where a creditor agency makes requests for offset.* Requests for offset under this section shall be sent to the Federal Labor Relations Authority, ATTN: Office of the Executive Director, 1400 K Street NW., Washington, DC 20424.

(d) *Incomplete certification.* The FLRA will return an incomplete debt certification to the creditor agency with notice that the creditor agency must comply with paragraph (b) of this section before action will be taken to collect a debt from a payment issued by the FLRA.

(e) *Review.* The FLRA is not authorized to review the merits of the creditor agency's determination with respect to the amount or validity of the debt certified by the creditor agency.

(f) *When the FLRA will not comply with offset request.* The FLRA will comply with the offset request of another agency unless the FLRA determines that the offset would not be in the best interests of the United States, or would otherwise be contrary to law.

(g) *Multiple debts.* When two or more creditor agencies are seeking offsets from payments made to the same person, or when two or more debts are owed to a single creditor agency, the FLRA may determine the order in which the debts will be collected or whether one or more debts should be collected by offset simultaneously.

(h) *Priority of debts owed to FLRA.* For purposes of this section, debts owed to the FLRA generally take precedence over debts owed to other agencies. The FLRA may determine whether to pay debts owed to other agencies before paying a debt owed to the FLRA. The FLRA will determine the order in which the debts will be collected based on the best interests of the United States.

### § 2418.20 What does the FLRA do upon receipt of a request to offset the salary of an FLRA employee to collect a debt owed by the employee to another Federal agency?

(a) *Notice to the FLRA employee.* When the FLRA receives proper certification of a debt owed by one of its employees, the FLRA will begin deductions from the employee's pay at the next officially established pay period. The FLRA will send a written notice to the employee indicating that a certified debt claim has been received from the creditor agency, the amount of the debt that the creditor agency claims is owed, the date deductions from salary will begin, and the amount of such deductions.

(b) *Amount of deductions from FLRA employee's salary.* The amount deducted under § 2418.19(b) will be the lesser of the amount of the debt certified by the creditor agency or an amount up to 15% of the debtor's disposable pay. Deductions shall continue until the FLRA knows that the debt is paid in full or until otherwise instructed by the creditor agency. Alternatively, the amount offset may be an amount that the debtor and the creditor agency agree upon in writing. See § 2418.12(g) (salary-offset process).

(c) *When the debtor is no longer employed by the FLRA*—(1) *Offset of final and subsequent payments.* If an FLRA employee retires or resigns or if his or her employment otherwise ends before collection of the debt is complete, then the FLRA will continue to offset, under 31 U.S.C. 3716, up to 100% of an employee's subsequent payments until the debt is paid or otherwise resolved. Such payments include a debtor's final salary payment, lump-sum leave payment, and other payments payable to the debtor by the FLRA. See 31 U.S.C. 3716 and 5 CFR 550.1104(l) and 550.1104(m).

(2) *Notice to the creditor agency.* If the employee is separated from the FLRA before the debt is paid in full, then the FLRA will certify to the creditor agency the total amount of its collection. If the FLRA is aware that the employee is entitled to payments from the Civil Service Retirement and Disability Fund, Federal Employee Retirement System, or other similar payments, then the FLRA will provide written notice to the agency making such payments that the debtor owes a debt (including the amount) and that the provisions of 5 CFR 550.1109 have been fully complied with. The creditor agency is responsible for submitting a certified claim to the agency responsible for making such payments before collection may begin. Generally, creditor agencies will collect such monies through the Treasury Offset Program as described in § 2418.9(c).

(3) *Notice to the debtor.* The FLRA will provide to the debtor a copy of any notices sent to the creditor agency under paragraph (c)(2) of this section.

(d) *When the debtor transfers to another Federal agency*—(1) *Notice to the creditor agency.* If the debtor transfers to another Federal agency before the debt is paid in full, then the FLRA will notify the creditor agency and will certify the total amount of its collection on the debt. The FLRA will provide a copy of the certification to the creditor agency. The creditor agency is responsible for submitting a certified claim to the debtor's new employing agency before collection may begin.

(2) *Notice to the debtor.* The FLRA will provide to the debtor a copy of any notices and certifications sent to the creditor agency under paragraph (d)(1) of this section.

(e) *Request for hearing official.* The FLRA will provide a hearing official upon the creditor agency's request with respect to an FLRA employee. See 5 CFR 550.1107(a).

## Appendix A to Part 2418—Waiving Claims Against FLRA Employees for Erroneous Payments

Date: May 1, 2015.

Subject: Waiving Claims Against FLRA Employees for Erroneous Payments.

1. Purpose

This appendix establishes the FLRA's policies and procedures for waiving claims by the Government against an employee for erroneous payments of: (1) Pay and allowances (*e.g.,* health and life insurance) and (2) travel, transportation, and relocation expenses and allowances.

2. Background

a. 5 U.S.C. 5584 authorizes the waiver of claims by the United States in whole or in part against an employee arising out of erroneous payments of pay and allowances, travel, transportation, and relocation expenses and allowances. A waiver may be considered when collection of the claim would be against equity and good conscience and not in the best interest of the United States, provided that there does not exist, in connection with the claim, an indication of fraud, misrepresentation, fault, or lack of good faith on the part of the employee or any other person having an interest in obtaining a waiver of the claim.

b. The General Accounting Office Act of 1996 (Pub. L. 104–316), Title I, section 103(d), enacted October 19, 1996, amended 5 U.S.C. 5584 by transferring the authority to waive claims for erroneous payments exceeding $1,500 from the Comptroller General of the United States to the Office of Management and Budget (OMB). OMB subsequently redelegated this waiver authority to the executive agency that made the erroneous payment. The authority to waive claims not exceeding $1,500, which was vested in the head of each agency prior to the enactment of Public Law 104–316, was unaffected by the Act.

c. 5 U.S.C. 5514 authorizes the head of each agency, upon a determination that an employee is indebted to the United States for debts to which the United States is entitled to be repaid at the time of the determination, to deduct up to 15%, or a greater amount if agreed to by the employee or a higher deduction has been ordered by a court under section 124 of Public Law 97–276 (96 Stat. 1195), from the employee's pay at officially established pay intervals in order to repay the debt.

3. Delegation

The Executive Director is delegated the authority to waive, in whole or in part, a claim of the United States against an employee for an erroneous payment of pay and allowances, travel, transportation, and relocation expenses and allowances, in accordance with the limitations and standards in 5 U.S.C. 5584.

4. Responsibilities

The Office of the Executive Director shall:

(1) Promptly notify an employee upon discovery of an erroneous payment to that employee;

(2) Promptly act to collect the erroneous overpayment, following established debt-collection policies and procedures;

(3) Establish time frames for employees to request a waiver in writing and for the Executive Director to review the waiver request. These time frames must take into consideration the responsibilities of the United States to take prompt action to pursue enforced collection on overdue debts, which may arise from erroneous payments.

(4) Notify employees whose requests for waiver of claims are denied in whole or in part of the basis for the denial.

(5) Pay a refund when appropriate if a waiver is granted;

(6) Fulfill all labor-relations responsibilities when implementing the provisions of this appendix; and

(7) Fulfill any other responsibility of the agency imposed by 5 U.S.C. 5584 or other applicable laws and regulations.

Additionally, the Office of the Executive Director may initiate a waiver application during the processing of a claim under 5 CFR part 2418.

5. Reporting Requirements

a. The FLRA shall maintain a register of waiver actions. The register shall cover each fiscal year and be prepared by December 31 of each year for the preceding fiscal year. The register shall contain the following information:

(1) The total amount waived by the FLRA;

(2) The number and dollar amount of waiver applications granted in full;

(3) The number and dollar amount of waiver applications granted in part and denied in part, and the dollar amount of each;

(4) The number and dollar amount of waiver applications denied in their entirety; and

(5) The number of waiver applications referred to the Executive Director for initial action.

b. The FLRA shall retain a written record of each waiver action for 6 years and 3 months. At a minimum, the written record shall contain:

(1) The FLRA's summary of the events surrounding the erroneous payment;

(2) Any written comments submitted by the employee from whom collection is sought;

(3) An account of the waiver action taken and the reasons for such action; and

(4) Other pertinent information such as any action taken to refund amounts repaid.

6. Effect of Request for Waiver

A request for a waiver of a claim shall not affect an employee's opportunity under 5 U.S.C. 5514(a)(2)(D) for a hearing on the determination of the agency concerning the existence or the amount of the debt, or the terms of the repayment schedule. A request by an employee for a hearing under 5 U.S.C. 5514(a)(2)(D) shall not affect an employee's right to request a waiver of the claim. The determination whether to waive a claim may be made at the discretion of the deciding official either before or after a final decision is rendered pursuant to 5 U.S.C. 5514(a)(2)(D) concerning the existence or the amount of the debt, or the terms of the repayment schedule.

7. Guidelines for Determining Requests

a. A request for a waiver shall not be granted if the deciding official determines there exists, in connection with the claim, an indication of fraud, misrepresentation, fault, or lack of good faith on the part of the employee or any other person having an interest in obtaining a waiver of the claim. There are no exceptions to this rule for financial hardship or otherwise.

(1) ''Fault'' exists if, in light of all the circumstances, it is determined that the employee knew or should have known that an error existed, but failed to take action to have it corrected. Fault can derive from an act or a failure to act. Unlike fraud, fault does not require a deliberate intent to deceive. Whether an employee should have known about an error in pay is determined from the perspective of a reasonable person. Pertinent considerations in finding fault include whether:

(a) The payment resulted from the employee's incorrect, but not fraudulent, statement that the employee should have known was incorrect;

(b) The payment resulted from the employee's failure to disclose material facts that were in the employee's possession and that the employee should have known to be material; or

(c) The employee accepted a payment, that the employee knew or should have known to be erroneous.

(2) Every case must be examined in light of its particular facts. For example, where an employee is promoted to a higher grade but the step level for the employee's new grade is miscalculated, it may be appropriate to conclude that there is no fault on the employee's part because employees are not typically expected to be aware of and understand the rules regarding determination of step level upon promotion. On the other hand, a different conclusion as to fault potentially may be reached if the employee in question is a personnel specialist or an attorney who concentrates on personnel law.

b. If the deciding official finds an indication of fraud, misrepresentation, fault, or lack of good faith on the part of the employee or any other person having an interest in obtaining a waiver of the claim, then the request for a waiver must be denied.

c. If the deciding official finds no indication of fraud, misrepresentation, fault, or lack of good faith on the part of the employee or any other person having an interest in obtaining a waiver of the claim, then the employee is not automatically entitled to a waiver. Before a waiver can be granted, the deciding official must also determine that collection of the claim against an employee would be against equity and good conscience and not in the best interests of the United States. Factors to consider when determining whether collection of a claim against an employee would be against equity and good conscience and not in the best interests of the United States include, but are not limited to:

(1) Whether collection of the claim would cause serious financial hardship to the employee from whom collection is sought.

(2) Whether, because of the erroneous payment, the employee either has relinquished a valuable right or changed positions for the worse, regardless of the employee's financial circumstances.

(a) To establish that a valuable right has been relinquished, it must be shown that the right was, in fact, valuable; that it cannot be

regained; and that the action was based chiefly or solely on reliance on the overpayment.

(b) To establish that the employee's position has changed for the worse, it must be shown that the decision would not have been made but for the overpayment, and that the decision resulted in a loss.

(c) An example of a ''detrimental reliance'' would be a decision to sign a lease for a more expensive apartment based chiefly or solely upon reliance on an erroneous calculation of salary, and the funds spent for rent cannot be recovered.

(3) The cost of collecting the claim equals or exceeds the amount of the claim;

(4) The time elapsed between the erroneous payment and discovery of the error and notification of the employee;

(5) Whether failure to make restitution would result in unfair gain to the employee;

(6) Whether recovery of the claim would be unconscionable under the circumstances.

d. The burden is on the employee to demonstrate that collection of the claim would be against equity and good conscience and not in the best interest of the United States.

8. Authorities

a. 5 U.S.C. 5584, ''Claims for Overpayment of Pay and Allowances, and of Travel, Transportation and Relocation Expenses and Allowances.''

b. 31 U.S.C. 3711, ''Collection and Compromise.''

c. 31 U.S.C. 3716, ''Administrative Offset.''

d. 31 U.S.C. 3717, ''Interest and Penalty on Claims.''

e. 5 CFR part 550, subpart K, ''Collection by Offset from Indebted Government Employees.''

f. 31 CFR part 5, subpart B, ''Salary Offset.''

g. Determination with Respect to Transfer of Functions Pursuant to Public Law 104–316, OMB, December 17, 1996.

9. Cancellation

FLRA Internal Regulation 2790, dated December 29, 1986, is superseded.

[FR Doc. 2015–09999 Filed 4–30–15; 8:45 am]

BILLING CODE 6727–01–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2015–0936; Directorate Identifier 2015–NM–058–AD; Amendment 39–18153; AD 2015–09–07]**

**RIN 2120–AA64**

## Airworthiness Directives; The Boeing Company Airplanes

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

**ACTION:** Final rule; request for comments.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for all The Boeing Company Model 787 airplanes. This AD requires a repetitive maintenance task for electrical power deactivation on Model 787 airplanes. This AD was prompted by the determination that a Model 787 airplane that has been powered continuously for 248 days can lose all alternating current (AC) electrical power due to the generator control units (GCUs) simultaneously going into failsafe mode. This condition is caused by a software counter internal to the GCUs that will overflow after 248 days of continuous power. We are issuing this AD to prevent loss of all AC electrical power, which could result in loss of control of the airplane.

**DATES:** This AD is effective May 1, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of May 1, 2015.

We must receive comments on this AD by June 15, 2015.

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

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

For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this 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. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0936.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0936; 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 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:** Kelly McGuckin, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6490; fax: 425–917–6590; email: *Kelly.McGuckin@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Discussion

We have been advised by Boeing of an issue identified during laboratory testing. The software counter internal to the generator control units (GCUs) will overflow after 248 days of continuous power, causing that GCU to go into failsafe mode. If the four main GCUs (associated with the engine mounted generators) were powered up at the same time, after 248 days of continuous power, all four GCUs will go into failsafe mode at the same time, resulting in a loss of all AC electrical power regardless of flight phase.

### FAA's Determination

We are issuing 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.

### AD Requirements

This AD requires a repetitive maintenance task for electrical power deactivation.

### Interim Action

We consider this AD interim action. The manufacturer is currently developing a GCU software upgrade that will address the unsafe condition identified in this AD. Once this software is developed, approved, and available, we might consider additional rulemaking.

### FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule. If the four main GCUs were

powered up at the same time, after 248 days of continuous power, all four GCUs will go into failsafe mode at the same time, resulting in a loss of all AC electrical power regardless of flight phase. Loss of all AC electrical power can result in loss of control of the airplane. Therefore, we find that notice and opportunity for prior public comment are impracticable and that good cause exists for making this amendment effective in less than 30 days.

## Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2015–0936 and Directorate Identifier 2015–NM–058–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this 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 AD.

## Related Service Information Under 1 CFR Part 51

We reviewed Boeing Multi Operator Message MOM–MOM–15–0248–01B, dated April 19, 2015; and Boeing Multi Operator Message MOM–MOM–15–0248–01B(R1), dated April 20, 2015. The service information describes procedures for electrical power deactivation of Model 787 airplanes. This service information is reasonably available at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0936. Or see **ADDRESSES** for other ways to access this service information.

## Costs of Compliance

We estimate that this AD affects 28 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---|---|---|---|---|
| Electrical power deactivation. | 1 work-hour × $85 per hour = $85 per deactivation cycle. | $0 | $85 per deactivation cycle ..... | $2,380 per deactivation 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

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

For the reasons discussed above, I certify that this AD:

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

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

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

## Adoption of the Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**2015–09–07 The Boeing Company:** Amendment 39–18153; Docket No. FAA–2015–0936; Directorate Identifier 2015–NM–058–AD.

**(a) Effective Date**

This AD is effective May 1, 2015.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all The Boeing Company Model 787 airplanes, certificated in any category.

**(d) Subject**

Air Transport Association (ATA) of America Code 24, Electrical power.

**(e) Unsafe Condition**

This AD was prompted by the determination that a Model 787 airplane that has been powered continuously for 248 days can lose all alternating current (AC) electrical power due to the generator control units (GCUs) simultaneously going into failsafe mode. This condition is caused by a software counter internal to the GCUs that will overflow after 248 days of continuous power. We are issuing this AD to prevent loss of all AC electrical power, which could result in loss of control of the airplane.

**(f) Compliance**

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

**(g) Repetitive Maintenance Task: Electrical Power Deactivation**

At the latest of the times specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, accomplish electrical power deactivation on

the airplane, in accordance with step 2) in ''DESIRED ACTION'' of Boeing Multi Operator Message MOM–MOM–15–0248–01B, dated April 19, 2015; or Boeing Multi Operator Message MOM–MOM–15–0248–01B(R1), dated April 20, 2015. The main and auxiliary power unit (APU) batteries do not need to be disconnected when performing the electrical power deactivation. Repeat the electrical power deactivation thereafter at intervals not to exceed 120 days.

(1) Within 120 days after the last electrical power deactivation in accordance with step 2) in ''DESIRED ACTION'' of Boeing Multi Operator Message MOM–MOM–15–0248–01B, dated April 19, 2015; or Boeing Multi Operator Message MOM–MOM–15–0248–01B(R1), dated April 20, 2015.

(2) Within 120 days after the date of issuance of the original certificate of airworthiness or the date of issuance of the original export certificate of airworthiness.

(3) Within 7 days after the effective date of this AD.

**(h) Special Flight Permit**

Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

**(i) 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 paragraph (j) 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.

**(j) Related Information**

For more information about this AD, contact Kelly McGuckin, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6490; fax: 425–917–6590; email: *Kelly.McGuckin@faa.gov.*

**(k) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Multi Operator Message MOM–MOM–15–0248–01B, dated April 19, 2015. The date appears only on the first page of this document.

(ii) Boeing Multi Operator Message MOM–MOM–15–0248–01B(R1), dated April 20, 2015. The date appears only on the first page of this document.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this 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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 23, 2015.

**Jeffrey E. Duven,**

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

[FR Doc. 2015–10066 Filed 4–30–15; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD; Amendment 39–18149; AD 2014–17–08R1]**

**RIN 2120–AA64**

## Airworthiness Directives; Pratt & Whitney Canada Corp. Turboprop Engines

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

**ACTION:** Final rule.

**SUMMARY:** We are revising airworthiness directive (AD) 2014–17–08 for all Pratt & Whitney Canada Corp. (P&WC) PT6A–114 and PT6A–114A turboprop engines. AD 2014–17–08 required initial and repetitive borescope inspections (BSIs) of compressor turbine (CT) blades, and the removal from service of blades that fail inspection. This new AD adds an additional single crystal CT blade, reduces the affected population, and corrects the Credit for Previous Action paragraph. This AD was prompted by P&WC development of an additional single crystal CT blade that corrects the unsafe condition. We are issuing this AD to prevent failure of CT blades, which could result in damage to the engine and damage to the airplane.

**DATES:** This AD is effective June 5, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain other publications listed in this AD as of October 8, 2014 (79 FR 52172, September 3, 2014).

**ADDRESSES:** For service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Internet: *www.pwc.ca.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125. Certain service information is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0766.

**Examining the AD Docket**

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0766; 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 AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Barbara Caufield, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7146; fax: 781–238–7199; email: *barbara.caufield@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to revise AD 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014), (''AD 2014–17–08''). AD 2014–17–08 applied to all P&WC PT6A–114 and PT6A–114A turboprop engines. The NPRM published in the **Federal Register** on December 1, 2014 (79 FR 71031). The NPRM was prompted by P&WC development of an additional single crystal CT blade that corrects the unsafe condition. The addition of this new part number (P/N) reduces the affected population. The NPRM proposed to retain all the requirements of AD 2014–17–08. The NPRM also proposed to add

the additional single crystal CT blade that corrects the unsafe condition, reduce the affected population, and correct the Credit for Previous Action paragraph. We are issuing this AD to prevent failure of CT blades, which could result in damage to the engine and damage to the airplane.

**Comments**

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 71031, December 1, 2014) and the FAA's response to each comment.

**Request To Clarify Disposition of Removed CT Blades**

Hawkins Aero Engineering, Inc. and another commenter requested that we state more clearly whether pre-SB (service bulletin) PT6A–72–1669 CT blades removed as a result of this AD can be reinstalled in the same engine, the same model engine, or a different model engine.

We disagree. Paragraph (e)(1)(iii)(B) of this AD clearly states that to re-install removed pre-SB PT6A–72–1669 CT blades, the blades must pass a two-blade metallurgical inspection to determine airworthiness in accordance with paragraph 3.B., Accomplishment Instructions, of P&WC Service Bulletin (SB) No. PT6A–72–1669, Revision 9, dated June 28, 2013. We did not change this AD.

**Request To Not Mandate Installation of Single Crystal CT Blades**

One commenter requested that we not mandate the installation of single crystal CT blades because two of the P/Ns cited as replacement blades have experienced low-time failures, indicating a design or manufacturing flaw.

We disagree. While there have been some failures of single crystal CT blades on a different engine model, that failure mode is well understood and does not affect the engines that are the subject of this AD. For the engines that are subject to this AD, single crystal blades provide a significant improvement in durability and a significant reduction in CT blade failures overall. We did not change this AD.

**Request To Reference Two Additional SBs**

One commenter requested that we reference P&WC SBs No. PT6A–72–1727 and No. PT6A–72–1749 in addition to P&WC SB No. PT6A–72–1669 because each one of these SBs references one of the three single crystal CT blades that can be installed as terminating action to this AD. P&WC SB No. PT6A–72–1669 alone only references one of the three blades listed as terminating action in paragraph (e)(2) of this AD.

We agree. We added references to the two additional SBs in paragraph (h)(2) of this AD.

**Request To Include Alternative Method of Compliance (AMOC) for Inspections**

Hawkins Aero Engineering, Inc. requested that we include in the AD an AMOC to allow a visual inspection, accomplished by splitting the engine at the C-flange, as an alternative method to the required periodic borescope inspection of pre-SB PT6A–72–1669 CT blades. The commenter states that this suggested visual method would provide easier detection of cracks.

We disagree. This AD contains the required method for resolving the unsafe condition. If an operator can accomplish required actions in a better way, or a way that better suits the operator's business processes, and the alternative method provides an acceptable level of safety, then the operator can apply for an AMOC to use that method to address the unsafe condition in accordance with paragraph (g)(2) of this AD. We did not change this AD.

**Request That We Address Failures in Additional Blades**

Hawkins Aero Engineering, Inc. requested that we address single crystal CT blade failures either in this or in another AD because there have been several low-time single crystal CT blade failures in several different PT6 engine models, some of which are single engine installations.

We disagree. Low-time failures that occurred on engine models not affected by this AD are due to a failure mode that is well understood. That failure mode does not occur in the engine models that are the subject of this AD. We did not change this AD.

**Conclusion**

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 71031, December 1, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in NPRM (79 FR 71031, December 1, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

**Costs of Compliance**

We estimate that this AD affects 300 engines installed on airplanes of U.S. registry. We also estimate that it would take about 4 hours per engine to perform the required inspection and 8 hours to replace the blades. The average labor rate is $85 per hour. Required parts cost about $59,334 per engine. Based on these figures, we estimate the cost of this AD on U.S. operators to be $18,106,200.

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

For the reasons discussed above, I certify that this AD:

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

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

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

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

## List of Subjects in 14 CFR Part 39

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

## Adoption of the Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014), and adding the following new AD:

**2014–17–08R1 Pratt & Whitney Canada Corp.:** Amendment 39–18149; Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD.

**(a) Effective Date**

This AD is effective June 5, 2015.

**(b) Affected ADs**

This AD replaces AD 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014).

**(c) Applicability**

This AD applies to all Pratt & Whitney Canada Corp. (P&WC) PT6A–114 and PT6A–114A turboprop engines.

**(d) Unsafe Condition**

This AD was prompted by several incidents of compressor turbine (CT) blade failure, causing power loss, and engine failure. We are issuing this AD to prevent failure of CT blades, which could lead to damage to the engine and damage to the airplane.

**(e) Compliance**

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

(1) For engines installed with CT blades other than P&WC single crystal CT blades, part numbers (P/Ns) 3072791–01, 3072791–02, or 3079351–01, do the following:

(i) Until removed, per the requirements of this AD, borescope inspect the CT blade leading and trailing edges, within the following intervals, whichever occurs later:

(A) 150 operating hours after October 8, 2014; or

(B) 500 operating hours since new; or

(C) 500 operating hours since last borescope inspection (BSI) of the CT blades; or

(D) Before next flight after the effective date of this AD.

(ii) Thereafter, repeat the inspection required by paragraph (e)(1)(i) of this AD every 500 flight hours time since last inspection.

(iii) At the next hot section inspection (HSI) after the effective date of this AD, and each HSI thereafter, replace the complete set of CT blades with any of the following:

(A) New CT blades;

(B) CT blades that have passed a two-blade metallurgical inspection. Use paragraph 3.B., Accomplishment Instructions, of P&WC Service Bulletin (SB) No. PT6A–72–1669, Revision 9, dated June 28, 2013, to do the inspection; or

(C) P&WC single crystal CT blades, P/N 3072791–01, 3072791–02, or 3079351–01.

(2) Replacement of the complete set of CT blades with single crystal CT blades, P/N 3072791–01, 3072791–02, or 3079351–01 is terminating action for the requirements of paragraph (e)(1) of this AD.

(3) By October 8, 2017, replace the complete set of CT blades with P&WC single crystal CT blades, P/N 3072791–01, 3072791–02, or 3079351–01.

**(f) Credit for Previous Action**

Performance of the metallurgical examination specified in paragraph (e)(1)(iii)(B) of this AD on CT blades other than P&WC single crystal CT blades, P/N 3072791–01, 3072791–02, or 3079351–01, before the effective date of this AD fulfills the initial inspection requirements of paragraph (e)(1)(i) of this AD. However, you must still comply with the repetitive BSI requirement of paragraph (e)(1)(ii) of this AD until you complete the mandatory terminating action of paragraph (e)(3) of this AD.

**(g) Alternative Methods of Compliance (AMOCs)**

(1) AMOCs previously approved for AD 2014–17–08, Amendment 39–17961 (79 FR 52172, September 3, 2014) are approved for this AD.

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

**(h) Related Information**

(1) For more information about this AD, contact Barbara Caufield, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7146; fax: 781–238–7199; email: *barbara.caufield@faa.gov.*

(2) P&WC SB No. PT6A–72–1727, dated August 23, 2013, and SB No. PT6A–72–1749, dated September 23, 2014, which are not incorporated by reference in this AD, can be obtained from P&WC using the contact information in paragraph (i)(4) of this AD.

**(i) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on October 8, 2014 (79 FR 52172, September 3, 2014).

(i) Pratt & Whitney Canada Service Bulletin No. PT6A–72–1669, Revision 9, dated June 28, 2013.

(ii) Reserved.

(4) For P&WC service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Internet: *www.pwc.ca.*

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

(6) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on April 17, 2015.

**Thomas A. Boudreau,**

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

[FR Doc. 2015–10075 Filed 4–30–15; 8:45 am]

BILLING CODE 4910–13–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2015–0794; Airspace Docket No. 15–ASO–5]**

## Proposed Amendment of Class E Airspace; Jupiter, FL

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** This action amends Class D Airspace at Jupiter, FL, by removing reference to Restricted Area R–2936 in the regulatory text of the Class D airspace area as the restricted area is no longer needed. This action also updates the geographic coordinates of the airport.

**DATES:** Effective 0901 UTC, June 25, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

**ADDRESSES:** FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/*

*airtraffic/publications/*. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783.

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

**SUPPLEMENTARY INFORMATION:**

### Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Y, airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this final rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

### The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by removing reference to Restricted Area R–2936 from the regulatory text of the Class D airspace area at William P. Gwinn Airport, Jupiter, FL, as the restricted area is no longer needed. This action also updates the airport's geographical coordinates to be in concert with the FAA's aeronautical database.

This is an administrative change and does not affect the boundaries, or operating requirements of the airspace, therefore, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it further clarifies the description of controlled airspace at William P. Gwinn Airport, Jupiter, FL.

### Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

### § 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, effective September 15, 2014, is amended as follows:

*Paragraph 5000 Class D Airspace*

* * * * *

**ASO FL D Jupiter, FL**

William P. Gwinn Airport, FL
(Lat.26°54′29″ N.,long.80°19′42″ W.)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.1-mile radius of William P. Gwinn Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

Issued in College Park, Georgia, on April 21, 2015.

**Gerald E. Lynch,**

*Acting Manager, Operations Support Group, Eastern service Center, Air Traffic Organization.*

[FR Doc. 2015–09881 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–13–P**

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## DEPARTMENT OF THE INTERIOR

## Office of Natural Resources Revenue

## 30 CFR Parts 1206 and 1210

**[Docket No. ONRR–2014–0001; DS63610000 DR2PS0000.CH7000 156D0102R2]**

**RIN 1012–AA15**

## Indian Oil Valuation Amendments

**AGENCY:** Office of Natural Resources Revenue (ONRR), Interior.

**ACTION:** Final rule.

**SUMMARY:** ONRR is amending its regulations governing the valuation, for royalty purposes, of oil produced from Indian leases. This rule will expand and clarify the major portion valuation requirement found in the existing regulations for oil production. This rule represents the recommendations of the Indian Oil Valuation Negotiated Rulemaking Committee (Committee). This rule also changes the form filing requirements necessary to claim a transportation allowance for oil produced from Indian leases.

**DATES:** *Effective date:* July 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** For questions on technical issues, contact John Barder at (303) 231–3702, Karl Wunderlich at (303) 231–3663, or Elizabeth Dawson at (303) 231–3653, ONRR.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The purpose of implementing this final rule regarding the valuation of oil production from Indian leases is: (1) To ensure that Indian mineral lessors receive the maximum revenues from mineral resources on their land consistent with the Secretary of the Interior's (Secretary) trust responsibility and lease terms and (2) to provide simplicity, certainty, clarity, and consistency for Indian oil valuation for Indian mineral revenue recipients and Indian mineral lessees.

## II. Comments on Proposed Rule

On June 19, 2014, ONRR published a Notice of Proposed Rulemaking (79 FR 35102) to amend the valuation regulations for oil production from Indian leases. The proposed rule represents the recommendations of the Indian Oil Valuation Negotiated Rulemaking Committee (Committee). The proposed rulemaking provided for a 60-day comment period, which ended on August 18, 2014. During the public comment period, ONRR received fifteen written comments: two responses from industry, three from industry trade groups or associations, three from Indian Tribes, four from individual Indian mineral owners, and three from unassociated individuals.

ONRR has carefully considered all of the public comments that it received during the rulemaking process. ONRR hereby adopts final regulations governing the valuation of oil produced from Indian leases. These regulations will apply, prospectively, to oil produced on or after the effective date that we have specified in the **DATES** section of this preamble.

This final rule reflects other changes to the proposed rule. In the preamble of the proposed rule, ONRR requested comments on: (1) Eliminating the current regulation's requirement that a lessee must file a Form ONRR–4110 to claim an arm's-length transportation allowance, which would mirror the Indian gas valuation rule at 30 CFR 1206.178(a)(1)(i); (2) removing the current rule's requirement that lessees reporting non-arm's-length transportation arrangements submit a Form ONRR–4110 with estimated information prior to taking the transportation allowance, again this change would mirror the Indian gas valuation rule found at § 1206.178(b)(2)(i); (3) eliminating a lessee's ability to use transportation factors in calculating its royalties due under § 1206.57, and, instead, requiring lessees to report all transportation costs as separate entries for transportation allowances on Form ONRR–2014; and (4) removing the ability for a lessee to request to exceed the 50-percent limitation on transportation allowances. As we discuss in more detail below, ONRR amended the current rule to (1) eliminate form filing requirements for arm's-length transportation allowances and (2) eliminate the pre-filing of Form ONRR–4110 prior to claiming a non-arm's-length transportation allowance.

### *A. General Comments*

ONRR received fifteen comments on the new rule. The majority of commenters expressed support for the rule. Other general comments fall into three categories: (1) ONRR's trust responsibilities, (2) increased communication with Indian lessors, and (3) the rule's impact on Indian lease royalty rates.

#### 1. ONRR's Trust Responsibility

*Public Comment:* ONRR received two comments requesting that ONRR emphasize that the purpose of the proposed rule is to maximize revenues to Indian lessors under Interior's trust responsibility. A Tribe indicated that ONRR also should modify the language in the preamble of the final rule to mirror the language that is in the proposed Indian gas rule to clarify that the purpose of the rule is to maximize revenues for the Indian lessor.

In contrast, an individual commenter disputed the proposed rule because the commenter believes that the Tribes, not ONRR, should be establishing oil prices on Indian lands. The commenter stated that the Secretary's role is solely to approve or disapprove Indian agreements and should not take on any fiduciary responsibilities.

*ONRR Response:* ONRR has included language in the preamble of the final rule that states that the purpose of the rule is to maximize revenues for the Indian lessor, mirroring language contained in the preamble of the Indian gas valuation rule.

The United States Government has a unique legal relationship with American Indian Tribal governments, stemming from the Constitution of the United States. Over time, treaties, Federal statutes, regulations, and court decisions have refined the relationship to be one that is committed to protecting and respecting the rights of self-government of sovereign Tribal governments. Thus, Federal Indian statutes and regulations have evolved to rest certain obligations on the Federal Government.

The Indian Mineral Leasing Act of 1938, 25 U.S.C 396a–396g, grants the Secretary the authority to oversee the leasing and development of Indian mineral resources. By enacting the Indian Mineral Leasing Act, Congress intended the Secretary to act as a trustee to Tribes and Indian mineral owners. *Jicarilla Apache Tribe* v. *Supron Energy Corp.,* 728 F.2d 1555, 1565 (10th Cir.1984) (Seymour, J., concurring in part and dissenting in part), adopted as majority opinion as modified en banc, 782 F.2d 855 (10th Cir.1986), supplemented, 793 F.2d 1171 (10th Cir. 1986), cert. denied, 479 U.S. 970 (1986). As a trustee, when ''faced with a decision for which there is more than one 'reasonable' choice as that term is used in administrative law, [the Secretary] must chose the alternative that is in the best interests of the Indian tribe.'' *Jicarilla* v. *Supron, Id.* at 1567.

Furthermore, Tribes and individual Indian mineral owners can negotiate mineral leasing agreements under the Indian Mineral Development Act of 1982, 25 U.S.C. 2101–2108. Consistent with principles of self-determination, Tribes and individual Indian mineral owners, through Tribal affiliation, can negotiate valuation terms in their leases, subject to Secretarial approval. The Secretary has a duty to administer Indian oil and gas leases, including enforcing royalty obligations under those leases.

#### 2. Increased Communication With Indian Lessors

*Public Comment:* ONRR received a comment seeking amendment to the rule requiring lessees to provide daily oil production reports. The commenter stated that daily oil production reports would ''ensure the timely marketing of the produced oil and that the production cycle is not interrupted.''

*ONRR Response:* ONRR appreciates the comment. The comment, however, is beyond the scope of this rulemaking, which is limited to the valuation of oil produced from Indian leases. ONRR receives monthly oil and gas reports, which are sufficient for us to ensure proper production verification and accountability. Through audits and other compliance activities, ONRR can, if necessary, obtain daily information to verify that lessees have properly accounted for and reported their Indian oil production.

*Public Comment:* ONRR received two comments seeking improved access to data to allow Indian lessors to monitor their leases—by wells—on a monthly basis. Both commenters felt that the Explanation of Payment Report (EOP) that the Bureau of Indian Affairs currently sends with royalty payments to Indian lessors on a monthly basis is insufficient to provide a clear picture of the Indian lessor's oil and gas production. One commenter felt that ONRR should post individual well information on its Web site for Indian lessors to monitor their leases.

*ONRR Response:* ONRR appreciates the comment. The comment, however, is beyond the scope of this rulemaking, which is limited to the valuation of oil produced from Indian leases. Under the Federal Oil and Gas Royalty Management Act (FOGRMA), the Secretary must provide an EOP when a lessee makes any payment to an Indian lessor. 30 U.S.C. 1715. The Secretary

must include ''a description of the type of payment being made, the period covered by such payment, the source of such payment, production amounts, the royalty rate, unit value and such other information as may be agreed upon by the Secretary and the recipient State, Indian tribe, or Indian allottee.'' *Id.*

ONRR generally does not receive royalty payment information by well because the information is voluminous and can include multiple leases, multiple communitization areas, and multiple lessors. And the lease, not the well, typically provides the basis for financial reporting, including financial terms against which ONRR assures compliance by companies and distributes royalties to Indian lessors.

Furthermore, the rule will require ONRR to post Index-Based Major Portion (IBMP) prices on its Web site. Thus, the proposed rule will increase the capacity for Indian lessors to validate the royalties that they receive are accurate. For applicable leases, if the volume-weighted price shown on the EOP is less than the IBMP value posted on ONRR's Web site, the Tribe and/or individual Indian mineral owner will know that there is a discrepancy based on the value of oil, the volume of the oil, and the lease's royalty rate.

3. The Rule's Impact on Indian Lease Royalty Rates

*Public Comment:* ONRR received two comments regarding the royalty rates in the leases. One commenter stated that ''the proposed rule leaves no ability for the lessor to negotiate a rate when the opportunity presents itself.'' Another stated that ''the Secretary has refused to negotiate royalty rates for which the Secretary is responsible.''

*ONRR Response:* ONRR appreciates the comments. The royalty rate, however, is a clause in the lease and is not a component of the proposed rule. Under the Indian Mineral Development Act, Tribes and individual Indian mineral owners are free to negotiate lease terms with potential lessees, subject to Secretarial approval. 25 U.S.C. 2102. The proposed rule does not limit or otherwise infringe on the authority of Tribes to negotiate those leases. The BIA regulations set out a minimum royalty rate, *see* 25 CFR 211.41(b); 212.41(b), and Indian lessors are free to negotiate a higher royalty rate. Nothing in this rule prevents Indian lessors from doing so.

*Public Comment:* In addition, a Tribal commenter stated that the proposed rule implicitly states that the Secretary's trust responsibility will not apply to Tribes in Eastern Oklahoma because the rule is not applicable to District Court leases, which do not contain a major portion provision or provide for Secretarial discretion to determine value.

*ONRR Response:* The purpose of the rule is to provide a method to calculate value under the major portion provision found in most Indian leases. The rule does not change how to value Indian oil on leases that do not contain a major portion provision. The commenter is correct that the rule will not apply to District Court leases because those leases do not contain a major portion provision or provide for Secretarial discretion to determine value. Therefore, valuing Indian oil produced from these leases will not change under the proposed rule. Indian lessors remain free to negotiate their royalty rates. And, as stated previously, the rule does not alter a lessor's ability to negotiate new leases or lease terms.

*B. Specific Comments on 30 CFR Part 1206—Product Valuation, Subpart B—Indian Oil*

1. How ONRR Calculates the LCTD

*Public Comment:* ONRR received a comment recommending that ONRR use an ''Adjustment Ratio (AR)'' instead of the Location and Crude Type Differential (LCTD). The commenter proposes an AR as the ratio of the Major Portion Price to the New York Mercantile Exchange (NYMEX) Calendar Monthly Average (CMA), which would be equal to the LCTD, but would take fewer steps to calculate and, thus, decrease the chance of error.

*ONRR Response:* ONRR agrees with the commenter that the initial Adjustment Ratio (AR) would return the same result as the initial LCTD. The method used in the proposed rule, however, makes explicit use of the differential between the major portion price and NYMEX CMA so that those less familiar with the formula can clearly see how the Index-Based Major Portion is calculated. Therefore, ONRR will retain the LCTD in the final rule because it is more transparent.

*Public Comment:* ONRR received two comments regarding the LCTD. One commenter recommended amending the rule to eliminate the 10-percent adjustment mechanism for the LCTD. That commenter stated that, in months where lessees report more than 28 percent of the production as non-OINX (the gross proceeds that the lessee receives for volumes sold above the IBMP value), ONRR has the data that it needs to calculate the 75-percent major portion price. Thus, the commenter states that ONRR should use that number rather than the IBMP value because that is the price at which 75 percent of production was sold in the designated area. In months where lessees report volumes of a specific crude type in a particular designated area as non-OINX fall below 22 percent, the commenter proposes multiplying the AR by 0.98.

*ONRR Response:* The commenter correctly states that, in months where there is more than 28 percent of the production reported in a particular designated area for a specific crude type as non-OINX, ONRR has the price at which the 75th percentile of oil is sold. ONRR, however, disagrees that the Agency should use that price as the major portion price. First, the price will not be contemporaneous with the current production month. The commenter's recommendation will require ONRR to base the value of the Indian oil production on sales that occurred two production months prior to the current production month—effectively putting the IBMP price two months in arrears from the current reporting month. In contrast, the IBMP value uses the most recent NYMEX prices adjusted by the LCTD, which is contemporaneous with the production month. Thus, under the final rule, the data that ONRR uses results in an adjustment of the most recent NYMEX CMA price.

Second, the commenter does not clarify how ONRR would return to using an LCTD once the amount of production not reported as non-OINX falls below 28 percent. Instead, the commenter suggests using the commenter's original AR and multiplying that by 0.98 to adjust the IBMP value. As we discussed above, however, ONRR is not amending the rule to use the AR. And, this methodology falls outside of the recommendations of the Committee. Lastly, ONRR is unclear how the 0.98 adequately replaces the LCTD adjustment.

*Public Comment:* ONRR received another comment regarding the proposed rule's 10-percent adjustment to the LCTD. The commenter stated that the 10-percent adjustment appears arbitrary and does not take into account severe swings in the market.

*ONRR Response:* ONRR disagrees that the 10-percent adjustment mechanism is arbitrary. The Committee negotiated the 10-percent adjustment to allow ONRR to adjust the LCTD to reflect swings in the market. The Committee negotiated the 10-percent adjustment to ensure that the IBMP value will return to the 22-percent-to-28-percent range in the event that the IBMP value does fall outside of that range. The Committee, however, limited the adjustment to 10 percent to

prevent drastic swings in the LCTD from month to month.

2. How ONRR Calculates the IBMP Value

*Public Comment:* ONRR received multiple comments regarding how ONRR calculates the IBMP value. ONRR received one comment stating that the formula that ONRR uses to calculate the IBMP value is too complex and difficult for the Indian lessor to understand. The commenter further believes that the calculation is labor-intensive and susceptible to error.

*ONRR Response:* ONRR appreciates the comment. While the formula may appear complex, ONRR will calculate the IBMP value each month and post the value on our Web site. Industry will then report and pay royalties on the higher of its gross proceeds or the posted IBMP value. Like the Indian Gas Major Portion calculation, ONRR will automate the process with internal controls to mitigate the risk of error. ONRR will provide training to those Tribes who would like to better understand the rule and to industry, who must comply with the rule.

*Public Comment:* Other commenters raised concerns regarding ONRR's shift from defining the major portion price in an area to be the price at which 50 percent by volume plus one barrel of oil is sold to using the price at which 25 percent, plus one barrel, by volume (starting from the top) of oil in an area is sold. One industry commenter states the 75th percentile is not a ''major'' portion—a major portion would be the 50 percent plus one barrel used under the current rule.

*ONRR Response:* ONRR incorporated the 75th percentile as the major portion of production based on (1) consistency with the Indian gas valuation rule and (2) the agreement reached by Committee. The Committee spent a significant amount of time deliberating what to use as a major portion price. Representatives for the Indian lessors advocated for a major portion price using the 75th percentile. Industry supported a major portion price based on the 50th percentile. Ultimately, industry representatives agreed to the 75th percentile in exchange for the benefits of the rule, including but not limited to: (1) Reduced accounting and administrative costs; (2) certainty associated with meeting the major portion obligation in real time; (3) significant reduction in prior period adjustments; (4) simplified audits and related expenses; and (5) reduced administrative appeals and litigation. In return, Indian lessors receive (1) royalties on their oil production founded on an index-based price equivalent to a 25-percent major portion from the top or the gross proceeds that their lessees receive; (2) more predictable and transparent information on revenues that they can expect to receive; and (3) royalties based on the leases' major portion provision sooner and with fewer adjustments. The Committee agreed to use the price at which 25 percent or more of the oil from the top is sold as a reasonable compromise on the term ''major.'' The change in the major portion value is identical to the trade-off that ONRR and the Indian Gas Valuation Negotiation Rulemaking Committee agreed upon prior to adopting the final Indian Gas Valuation Rules in 1999. Industry representatives agreed to the change in exchange for clarity, certainty, and reduced administrative costs.

*Public Comment:* ONRR also received a comment from an individual asserting ONRR ''has not enforced the major portion provision or disclosed facts essential to understanding a claim. . . .''

*ONRR Response:* The final rule applies prospectively and will not impact ONRR's efforts to enforce the major portion provision under the prior rule.

*Public Comment:* One industry commenter noted that the 25-percent major price component in the rule will result in the commenter realizing the full 3.93-percent increase in royalties that ONRR estimated that industry would pay under the proposed rule.

*ONRR Response:* The 3.93 percent discussed in the preamble of the proposed rule is only to show, on average, the minimal impact of the proposed rule industrywide. The commenter's royalties may increase more or less than 3.93 percent.

*Public Comment:* ONRR also received a comment implying that the IBMP value is inadequate because it includes cost sharing. The commenter proposed to value oil produced from Indian lands by paying the Indian lessor 25 percent of the current NYMEX price, less the LCTD. The commenter stated that the LCTD should be allowed, but it should only capture the difference in value due to location and quality and that ONRR should eliminate any transportation allowances and any other costs/allowances. In so doing, the commenter states that ONRR will maximize the revenue of the Indian lessor.

*ONRR Response:* ONRR disagrees. ONRR maintains that the final rule maximizes revenues for Tribes and individual Indian mineral owners. The final rule ensures that the lessor receives the higher of (1) a value that approximates the major portion price at the 25th percentile by volume plus one barrel from highest price to lowest price, arrayed from the top (the top means that volume associated with the highest price that lessees receive for crude oil produced in a particular designated area in any given month); or (2) the gross proceeds accruing to the lessee. ONRR addresses the commenter's view on the elimination of transportation allowances under section 6 of the response to specific comments.

*Public Comment:* ONRR received three comments regarding the data that it uses to calculate the IBMP. Two Tribal commenters stated that ONRR must rely on audited data to calculate the initial LCTD for each designated area. The Tribal commenters are concerned that unaudited data may include inaccurate data that will have lingering and ongoing effects on the IBMP value. In contrast, ONRR received a comment from an individual stating that ONRR cannot go back and change the IBMP regardless if ONRR found errors in reported information.

*ONRR Response:* All oil production and sales reported to ONRR are subject to review and audit. Currently, ONRR has upfront edits, *i.e.* automated verifications, in place in our reporting systems, as well as data mining activities, which minimize inaccurately reported data. Moreover, as ONRR inputs the data that it uses to calculate the initial LCTD and future adjustments, ONRR will scrutinize the data to identify and resolve outliers as well as grossly misreported royalty volumes and values. Additionally, the large amount of data necessary to calculate the LCTD for any designated area will minimize the effects of individual misreported data. ONRR feels that these tools will adequately prevent bad data from influencing the initial LCTD calculation. In order to begin collecting royalties on the IBMP value, ONRR is using the previous 12 months of data collected. As we discussed above, ONRR will edit and scrutinize that data before using it in the formula. This approach represents a trade-off between using audited data, which can take three or more years to complete, and using the IBMP value formula, which results in contemporaneous payment of major portion obligations and early certainty for the Indian lessors.

3. ONRR's Discretion To Determine IBMP Value

In the preamble of the proposed rule, ONRR requested comments on whether ONRR should modify paragraph (e) of 30 CFR 1206.54 to provide that ONRR will use its discretion to determine an

appropriate IBMP value where there are insufficient lines reported to ONRR on Form ONRR–2014 to determine a differential for a specific crude oil type or when the LCTD varies more than +/- 20 percent. In addition, ONRR requested comments on what would constitute a significant variation.

*Public Comment:* ONRR only received one general comment on § 1206.54(e). The commenter recommended that ONRR uses the Indian oil valuation standards found in the current oil rule to guide ONRR's discretion to ensure that the IBMP value is tied to the express terms of the lease.

*ONRR Response:* The provision in § 1206.54(e) providing ONRR with discretion allows ONRR to calculate a value if, for unforeseen circumstances, the data in a particular designated area for a particular crude type would prevent ONRR from accurately calculating the IBMP value. ONRR would still rely on information regarding like-quality oil and the location of the lease to calculate an appropriate differential, consistent with the lease terms. For example, ONRR may use its discretion to review sales data from nearby Federal leases to calculate the differential in situations where a designated area may have insufficient data to calculate an LCTD. Furthermore, ONRR identified designated areas to ensure that there is adequate information provided in the Form ONRR–2014 to calculate the IBMP value.

ONRR decided not to adopt a rule providing us with the discretion to calculate an IBMP value when the LCTD varies more than +/ − 20 percent. Instead, we will use the final rule's LCTD 10-percent adjustment mechanism to approximate, as close as possible, the 25th percentile major portion price.

4. ONRR's Proposed Designated Areas

*Public Comment:* A Tribal commenter indicated that Oklahoma should not be a single designated area. The Tribal commenter is concerned that using Oklahoma as a single designated area does not take into account varying transportation costs and differences in the quality of oil.

*ONRR Response:* In evaluating whether to use the State of Oklahoma as a Designated Area, ONRR analyzed prices and crude types across Oklahoma. In performing the analysis, ONRR did not find that there were any significant differences in the quality of the oil and the price of the oil sufficient to warrant separate designated areas, and, hence, separate LCTD calculations. The proximity of the Indian oil producing leases in Oklahoma to Cushing, Oklahoma, (the market center that serves as the basis of the IBMP value under this rule) reduced the impact of the location differential on the price of the oil. ONRR performed an analysis for the Committee, showing that transportation costs throughout Oklahoma were relatively small and that such costs do not demonstrate a consistent cost difference between leases in close proximity to Cushing and those further away. Although the Designated Area of Oklahoma is in close proximity to Cushing, Oklahoma, ONRR concluded an LCTD was warranted for Oklahoma. Because of its proximity to Cushing, Oklahoma, however, the LCTD for Oklahoma will be minimal.

*Public Comment:* An individual commenter suggested that ONRR remove the Muscogee (Creek) Nation and the Seminole Nation's lands in Osage County, Oklahoma, and designate those lands as a ''Designated Area.''

*ONRR Response:* ONRR has confirmed that the Osage Nation owns all of the mineral rights in Osage County, Oklahoma. FOGRMA excludes Osage Indian lands. 30 U.S.C. 1702 (3). Therefore, ONRR cannot include Osage County as its own designated area or enforce the rule on Indian mineral production from Osage County, Oklahoma.

*Public Comment:* ONRR also received a comment from an industry commenter stating that ONRR has not provided the criteria it will use to determine when to modify or add designated areas. The commenter worries that there is no mechanism for industry ''to petition ONRR to modify a designated area in the event that the designated area contains diverse geography and distinguishable access to infrastructure (such as pipelines, rail lines, and trucking).''

*ONRR Response:* The final rule and the preamble of the proposed rule specifically address the commenter's concerns. The final rule at 30 CFR 1206.51 lists criteria that ONRR will use to determine any future changes to designated areas that are identical to the very criteria that the commenter lists. Such criteria include markets served (such as refineries and market centers) and access to infrastructure (including trucking, pipelines, or rail). 30 CFR 1206.151 (final rule).

Moreover, the preamble to the proposed rule states: ''If there is a significant change that affects the differentials for a designated area, affected Tribes, Indian mineral owners, or lessees/operators may petition ONRR to consider conveying a technical committee to review, modify, or add designated areas.'' 79 FR 35102; 35104 (Jun. 19, 2014). ONRR will look at the same criteria that we outlined in the final rule to determine any future changes to designated areas. *Id.*

*Public Comment:* The industry commenter also takes issue with the final rule's use of ''Designated Areas'' over ''fields'' to calculate a price for ONRR to use to calculate the major portion price. The commenter believes that the use of a designated area is inconsistent with the lease language.

*ONRR Response:* The primary purpose of creating the Committee was to come to a consensus on how to implement the major portion provision found in most Indian leases. Determining the geographic range of data to use to calculate a major portion provision was one of the most highly debated topics in the Committee meetings. As a general rule, Committee members who represented industry advocated for the use of specific fields to calculate a value of oil sold under the major portion provision. Alternatively, Tribes and allottees promoted a broader area focused more on an oil type than the geographic location of the lease. The debate turned to implementing the rule on a field level versus a broader area. Ultimately, the Committee agreed to use ''designated areas'' developed based on the set criteria defined in the final rule. All meeting presentations, handouts, and meeting minutes are available on the Committee Web site at *http://www.onrr.gov/Laws_R_D/IONR/.*

The commenter interprets the lease terms as requiring the Secretary to perform a major portion analysis solely on a field-by-field basis. Standard Indian lease forms commonly include a provision that states:

> During the period of supervision, ''value'' for the purposes hereof, may, in the discretion of the Secretary, be calculated on the basis of the highest price paid or offered . . . at the time of production for the major portion of the oil of the same gravity, and gas, and/or natural gasoline, and/or all other hydrocarbon substances produced from the field where the leased lands are situated . . .

Standard Indian Allotted Lease, para. 3(c)

The rationale of using an area over a field is to ensure that there is a reasonable sample of data to conduct a major portion analysis. ONRR must meet both the requirements of the major portion provision in the leases and the Trade Secrets Act. Under the Trade Secrets Act, ONRR cannot reveal or release information that can be considered a trade secret because doing so may cause competitive harm. The Department has adopted a policy that

financial and commercial data is proprietary. ONRR uses financial and commercial data that payors report to conduct a major portion analysis. Thus, ONRR has determined that, to perform a major portion analysis, it needs an area large enough to have at least three payors. Otherwise, it would be possible for a party to use the value data that ONRR provides with its calculations, combine it with other publicly available data, and determine the price that other industry members are selling their oil.

ONRR has consistently interpreted the Secretary's discretion language in Indian leases as allowing ONRR to evaluate the major portion price in areas as well as fields. *See* 30 CFR 1206.152; 1206.52; 1206.51; 30 CFR 206.103 (1984); and Notice to Lessees and Operators of Indian Oil and Gas Leases (NTL–1A), 42 FR 18135 (Apr. 5, 1977). In fact, under the Indian gas valuation rule, ONRR calculates the major portion price for Indian-gas-based designated areas similar to those proposed in this rule. *See* 30 CFR 1206.173(a)(2)(i) (2013).

The Navajo Nation Reservation provides an example of ONRR's reasoning to expand the field to a designated area. Ninety-seven percent of production on the Navajo Nation Reservation comes from one field and reservoir, the Greater Aneth Field in the Paradox Basin. Six payors report production from the Greater Aneth Field. The remaining 3 percent of production on the Navajo Nation Reservation comes from 24 fields with less than three payors on 22 of those 24 fields. The oil produced and sold on the Navajo Reservation is similar in all fields and is transported to the same refinery using similar transportation systems. Thus, to properly perform a major portion analysis for any oil production on the Navajo Reservation, ONRR expands the Designated Area to incorporate fields surrounding the Greater Aneth because the individual fields do not provide an appropriate sample size.

*Public Comment:* The same commenter next disputes ONRR's use of an entire reservation as a designated area. The commenter believes that using a reservation as a designated area fails to accurately account for local price differences and transportation costs that can vary within the reservation. The commenter uses the Navajo Nation Reservation as an example, illustrating the difficulties of obtaining accurate differentials. The commenter further states that it does not see that ONRR took into consideration geography and access to infrastructure within the reservations when we created the designated areas based on reservation boundaries.

*ONRR Response:* The Committee had exhaustive and extensive discussions regarding the amount and variation of transportation for each of the designated areas, including the factors that the commenter lists. As discussed above, ONRR evaluated the oil produced on the Navajo Nation Reservation, including the quality of the oil produced, transportation methods, and refineries used. Based on ONRR's analysis, the Committee determined that one Designated Area on the Navajo Nation Reservation adequately captured the differentials between oil produced on the reservation and oil sold in Cushing.

5. The Roll

*Public Comment:* ONRR received two comments in response to its request for comments on how ONRR changes the roll. ONRR sought comments on the flexibility of changing how it defines the roll or terminating the roll, with the caveat that it will publish any changes to the roll in the **Federal Register**. An industry commenter supported the ability for ONRR to terminate or redefine the roll only if such changes are published in the **Federal Register**, and ONRR provides industry the opportunity to comment on the proposed change. The second commenter suggested that ONRR eliminate the roll from its calculations altogether. The roll applies only to Indian oil produced in Oklahoma.

*ONRR Response:* ONRR will publish any changes to the roll in the **Federal Register** to provide notice and the opportunity for comment. ONRR incorporates the roll based on the agreement of the Committee and the fact that most contracts for oil sold from Indian leases in Oklahoma, which reference NYMEX prices, include the roll. Therefore, ONRR is keeping the roll in the final rule.

6. Transportation Allowances

*Public Comment:* ONRR received comments from five individual Indian mineral owners and one Tribe arguing that ONRR does not have the authority to include transportation allowances as part of the royalty equation.

*ONRR Response:* ONRR disagrees. The Act of June 30, 1834 (25 U.S.C. 9); the Act of March 3, 1909 (25 U.S.C. 396); the Indian Mineral Leasing Act of 1938 (25 U.S.C. 396a–396g); the Indian Mineral Development Act of 1982 (25 U.S.C. 2101, *et seq.*); and the FOGRMA (Pub. L. 97–451; 30 U.S.C. 1701 *et seq.*) authorize the Secretary to promulgate whatever regulations are necessary to implement those statutes.

The rationale for allowing lessees to deduct transportation costs comes from the language of the lease. Generally, Indian oil leases provide that the lessee will pay the Tribe or individual Indian mineral owner a certain percent of the ''value or amount of all oil, gas, and/or natural gasoline, and/or all other hydrocarbon substances *produced and saved from the land leased herein.''* See Standard Indian Allotted Lease, para. 3(c) (Emphasis added). In essence, transportation allowance accounts for the costs that a lessee must incur to move its production to a market and, therefore, captures the value at the lease. The lessor shares in this expense because the lessor reaps the benefit of selling its lease production at a market rather than at the wellhead. If the lessor were to take its royalties in kind (*i.e.* in barrels of oil), the lessor would then incur all of the cost of transporting the oil production to a market to sell the oil.

To comply with this provision, for decades ONRR's regulations have allowed a lessee to deduct its transportation costs to calculate the value of their Indian oil production when it sells that oil at a location remote from the lease. *See* 53 FR 1184 (Jan. 15, 1988) (promulgating rule incorporating transportation allowances to determine the value of Federal and Indian oil production, for royalty purposes). ONRR has consistently allowed transportation costs because transporting oil to market off of the lease increases the value of the oil.

Courts have upheld the use of transportation allowances as a means to calculate the value of oil production for royalty purposes. *See United States* v. *General Petroleum Corp. of California,* 73 F. Supp. 225, 262 (S.D. Cal. 1946), *aff'd sub nom Continental Oil Co.* v. *United States,* 184 F.2d 802 (9th Cir. 1950) (stating ''It has been held that if there is no open market in the place where an article ordinarily would be sold, the market value of such article in the nearest open market less cost of transportation to such open market becomes the market value of the article in question.''). The IBLA has confirmed allowing such deductions to Indian leases, consistent with Interior policy. *Kerr-McGee Corp.,* 22 IBLA 24 (1975).

*Public Comment:* One commenter claims that allowing lessees to deduct transportation allowances from the value of their oil is a taking that is prohibited by the Fifth Amendment of the U.S. Constitution.

*ONRR Response:* ONRR disagrees. Under the Fifth Amendment of the U.S. Constitution, the Federal government cannot deprive a person of ''life, liberty, or property, without due process of law;

nor shall private property be taken for public use, without just compensation.'' This provision is not violated or implicated by the final rule. This final rule will not impose conditions or limitations on the use of private property, and this final rule does not modify the current regulations to allow additional transportation costs. Therefore, this final rule does not result in a takings.

*Public Comment:* A Tribal commenter commented on using a statewide index for transportation costs in Oklahoma when the costs of transportation in the State will vary from location to location, thus ''increasing with distance from the point of sale.''

*ONRR Response:* The Committee debated the issue of whether to allow location differentials for Oklahoma as a designated area. As we stated previously, ONRR performed an analysis for the Committee showing that there were small amounts of transportation costs that Indian lessees claimed throughout Oklahoma. The analysis showed that, although there were small amounts of transportation in Oklahoma, such costs did not demonstrate a consistent cost difference between leases in close proximity to Cushing and those further away. ONRR found that a lease located within a few miles of Cushing may have a higher transportation cost than a lease hundreds of miles away. Although the Designated Area of Oklahoma is in close proximity to Cushing, Oklahoma, ONRR concluded that an LCTD was warranted for Oklahoma. However, because of its proximity to Cushing, Oklahoma, the LCTD for Oklahoma will be minimal.

7. Comments in Response to Other Proposed Changes to the Indian Oil Rule

In addition to the major portion component of the proposed Indian oil valuation rule, ONRR requested comments concerning amending some of the provisions governing transportation allowances. Specifically, ONRR requested comments on (1) eliminating the requirement under the current rule to file a Form ONRR–4110, Oil Transportation Allowance Report, for arm's-length transportation agreements, which would mirror the requirement to file arm's-length transportation contracts with ONRR—rather than a form—under the current Indian Gas Valuation Rule at 30 CFR 1206.178(a)(1)(i); (2) removing the requirement that lessees submit a Form ONRR–4110 for non-arm's-length transportation allowances in advance of claiming an allowance and, instead, submit actual cost information in support of the allowance on its Form ONRR–4110, again mirroring the current Indian Gas Rule; (3) eliminating transportation factors under § 1206.57(a)(5); and (4) eliminating a lessee's ability to request to exceed the 50-percent limitation on transportation allowances under the current rule at § 1206.56(b)(2).

*Public Comment:* Generally, commenters supported removing the form filing requirements for arm's-length transportation allowances. A couple of industry commenters, however, requested guidance on what types of agreements that ONRR would require in order to claim a transportation allowance and what format ONRR would accept the agreement to be in (hardcopy, email, flashdrive, etc.). A Tribal commenter recommended that ONRR require lessees to provide hard copies of their transportation contracts.

*ONRR Response:* The final rule mirrors the Indian Gas Valuation Rule and requires payors to file arm's-length transportation contracts with ONRR rather than Form ONRR–4110. *See* 30 CFR 1206.178(a)(1)(i). ONRR will provide guidance to payors on the acceptable types and forms of contracts on a case-by-case basis, taking into consideration the Indian lessor's preferences.

*Public Comment:* For non-arm's-length transportation allowances, ONRR received two comments in support of the change proposed. The Tribal commenter, however, requested that ONRR require lessees to notify ONRR in advance that the lessee will apply a non-arm's-length transportation allowance against the value of the oil production. The Tribal commenter feels that this notice would be helpful in identifying areas of risk and discouraging lessees from failing to report transportation allowances.

*ONRR Response:* ONRR appreciates the comment and suggestion. The Form ONRR–4110 does not require lessees to provide notice and, at this time, ONRR will not require lessees to provide notice. ONRR understands the Tribal commenter's concerns regarding reporting transportation allowances. Under the current rule and final rule, however, lessees must report any non-arm's-length transportation allowances as a separate line on Form ONRR–2014. Should any auditor find that a lessee is reporting its oil production net of a transportation allowances, the auditor should refer the matter to ONRR's Office of Enforcement. ONRR's Office of Enforcement will investigate, enforce the regulations, and, where necessary, issue civil penalties.

*Public Comment:* ONRR received three opposing comments from industry and one supporting comment from a Tribe in response to its request for comments to eliminate transportation factors.

*ONRR Response:* ONRR believes that the increased transparency associated with eliminating transportation factors will better facilitate (1) ONRR's monitoring of oil values and (2) the accuracy of those values. Because of the other more important aspects of this rule, however, and our desire to have consistency with the Indian gas valuation rule, ONRR has decided to pursue this issue in a future rulemaking for both Indian oil and gas production.

*Public Comment:* One commenter stated that it opposed eliminating transportation factors because it could not find a definition of a transportation factor. The commenter indicated it was impossible to comment without such a definition. Another industry commenter stated that ''transportation factors used for oil often include both a location and a quality differential, and it may not be possible to separate this factor between the two differentials.''

*ONRR Response:* The current rule does not provide a definition for a transportation factor. If an arm's-length contract price or posted price includes a provision by which the purchaser reduces the listed price to reflect the purchaser's transportation costs and then pays the lessee a net value under that arm's-length contract, ONRR deems the amount of the transportation reduction to be a transportation factor. A transportation factor is an actual transportation cost embedded in the arm's-length sales contract. *See* 30 CFR 1206.57. Because these actual transportation costs are part of what a lessee reports as the sales price of the oil that the lessee sells and are not separately reported transportation allowances, ONRR and its Indian lessors do not see the cost of transporting the oil to the point of sale as it would with transportation allowances. While ONRR believes that eliminating transportation factors increases transparency and certainty, ONRR has decided not to eliminate transportation factors in the final rule. Because of the more important aspects of the final rule and our desire to have consistency with the Indian gas valuation rule, ONRR has decided to pursue this issue in a future rulemaking for both Indian oil and gas production.

*Public Comment:* ONRR received three opposing comments from industry groups and one supporting comment from a Tribe in response to its request for comments on removing the

provision under 30 CFR 1206.56(b)(2) that allows lessees to request an exception of the 50-percent limitation on transportation allowances.

*ONRR Response:* The final rule retains a lessee's ability to request approval to exceed the 50-percent limitation on transportation allowances. Under the current rule and the final rule, ONRR has the authority to review each and every request to ensure that the exception still represents a lessee's reasonable, actual, and necessary transportation costs. To date, ONRR has yet to receive a request for a transportation allowance to exceed 50 percent of the value of the Indian oil production. At this time, ONRR does not anticipate it will begin to receive such requests. Should ONRR receive a request to exceed, however, the Agency will review the request and all data involved, then we will consult with the Indian lessor before deciding to allow the lessee to exceed 50 percent. ONRR believes that these controls satisfy its trust responsibility to the Indian lessor.

*C. Specific Comments on 30 CFR Part 1210—Forms and Reports, Subpart B—Royalty Reports—Oil, Gas, and Geothermal Resources*

ONRR did not receive comments specific to 30 CFR part 1210.

*D. Principal Changes*

Under the proposed rule, ONRR stated, ''for every month following the first full production month after this rule is effective, ONRR will monitor the LCTD using data reported on the Form ONRR–2014 for the previous month.'' ONRR discovered, however, that, because companies can report on estimates, significant volumes of Indian oil sales are not reported by the last day of the month following the month of production. ONRR allows lessees to make a one-time estimate of their monthly royalty obligation in order to report and pay future royalties two months following the month of production. ONRR monitors a lessee's monthly reporting to ensure that the estimate on file with ONRR is sufficient, and, if it is not, then ONRR bills the lessee for late payment interest for the amount of the estimate that is insufficient.

Because of these estimates, many lessees do not report a large volume of Indian oil sales by the last day of the month following the month of production, ONRR is modifying the rule to use data from two months prior to the production month to monitor whether we will adjust the LCTD. This change will ensure that the data that ONRR uses to adjust the LCTD captures the majority of oil sales for that particular production month. Because ONRR will require the sales data from two months prior to the production month, ONRR will not make any adjustments to the LCTD for the first two production months after the rule is in effect.

**III. Procedural Matters**

*1. Summary Cost and Royalty Impact Data*

We estimated the costs and benefits that this rulemaking may have on all potentially affected groups: Industry, Indian Lessors, and the Federal government. This amendment will result in an estimated annual increase in royalty collections of between $19.4 million and $20.6 million for ONRR to disburse to Indian lessors. This net impact represents a minimal increase of between 3.82 percent and 3.93 percent of the total Indian oil royalties that ONRR collected in 2012. We also estimate that Industry and the Federal government will experience one-time increased system costs of approximately $4.84 million and $247 thousand, respectively.

A. Industry

The table below lists ONRR's low, mid-range, and high estimates of the additional royalty costs that Industry will incur in the first year (excluding one-time system costs). Industry will incur these costs in the same amount each year thereafter.

SUMMARY OF ROYALTY IMPACTS TO INDUSTRY

| Low | Mid | High |
|---|---|---|
| $19,400,000 | $20,000,000 | $20,600,000 |

Cost—Using the Higher of the Index-Based Major Portion Formula Value or Gross Proceeds To Value Indian Oil Sales

As discussed above, the final rule contains a provision under 30 CFR 1206.54 that explains how a lessee must meet its obligation to value oil produced from Indian leases based on the highest price paid for a major portion of like-quality oil from the field. This rule defines the monthly IBMP value that a lessee must compare to its gross proceeds and pay on the higher of those two values.

To perform this economic analysis, ONRR used royalty data that we collected for Indian oil (product code 01) for calendar year 2012. We chose calendar year 2012 because most data reported has gone through ONRR edits and lessees have made most of their adjustments. We did not distinguish crude oil type within each designated area because (1), based on our experience, crude oil type within each designated area is generally the same, and (2) lessees currently do not report crude oil type to ONRR.

We then segregated the data into the following 14 designated areas:

1. Uintah and Ouray—Uintah and Grand Counties
2. Uintah and Ouray—Duchesne County
3. North Fort Berthold
4. South Fort Berthold
5. Oklahoma—One statewide area excluding Osage County
6. Fort Peck
7. Turtle Mountain
8. Blackfeet Indian Reservation
9. Crow Indian Reservation
10. Jicarilla Apache Indian Reservation
11. Isabella Indian Reservation (Saginaw Chippewa)
12. Navajo Indian Reservation
13. Ute Mountain Ute Indian Reservation
14. Wind River Indian Reservation

We first arrayed the monthly reported prices—net of transportation—from highest to lowest and then calculated the monthly major portion price as that price at which 25 percent plus 1 barrel (by volume) of the oil is sold (starting from the highest price). Next, we calculated the difference between the reported prices and the major portion price. For any price below the major portion price, we multiplied the price difference by the royalty volume to estimate additional royalties.

Lastly, we totaled all of the monthly additional royalties for each designated area and then totaled all of the areas to arrive at an additional average royalty amount of $20 million. This amount represents 3.70 percent of all Indian oil royalties collected in 2012, or, approximately, $0.558/bbl.

Of note, we did not use the LCTD in this analysis. The rule uses the LCTD to calculate the IBMP value, which keeps the gross proceeds volume near the 25th percentile, through monthly monitoring and adjustments to the LCTD. Rather, we used the actual monthly major portion price in our analysis. Because we used the actual monthly major portion price, we did not account for the potential +/− 3 percent volume variation adjustments that the rule would allow. Instead, we created a +/− 3 percent range of royalty impacts above and below the estimated additional royalties, reflected in the table above.

Cost—System Changes To Accommodate Reporting of Crude Oil Type

ONRR needs to know crude oil types to calculate and publish the IBMP value.

Therefore, § 1210.61 requires a lessee to report crude oil types using new product codes on Form ONRR–2014. ONRR anticipates that a lessee will make computer system changes to add these new product codes to their automated reporting.

We identified 205 Indian payors (those reporting and paying royalties to ONRR) in 2012. Of those, ONRR identified 32 as large businesses and 173 as small businesses (based on the SBA definition of a small business having 500 employees or fewer). To more accurately reflect the Indian payor community—based on our experience, we reclassified the 173 small businesses into two categories: Medium and small companies. We defined a medium company as those companies with between 250 and 500 employees. We also defined small companies as those companies with 250 or fewer employees. We classified 58 companies as medium companies and 115 companies as small companies.

ONRR first identified the changes that we must make to our systems in order to accommodate the requirements (adding product codes and edits, changing and adding reports, and modifying Oil and Gas Operations Reports, Form ONRR–4054 (OGORs)) of this rule and then estimated the number of hours needed to make those changes. We then multiplied those hours by our estimated hourly cost (including contractors) to implement system changes. Some of the hours calculated for ONRR include costs that Industry would not incur, such as eCommerce updates, changes to the compliance management tool, and web publishing.

We used this same process for large businesses, reducing or eliminating the hours for some categories, but used the same hourly cost because most large companies employ system contractors similar to those ONRR employs and, therefore, would have similar system change costs.

We reduced the hours for the medium (200 hours) and small companies (100 hours) to reflect the fact that their systems are smaller and less complex. We also reduced the hourly rate for medium and small businesses to $100 and $75, respectively, reflecting lower contractor costs. The table below provides our estimate of system change costs for both ONRR and Industry.

| System changes | ONRR | Large business | Medium business | Small business |
|---|---|---|---|---|
| Adding product codes to ONRR 2014–PS | 100 | 100 | 100 | 50 |
| Adding product codes to ONRR 2014–eCommerce | 100 | 0 | 0 | 0 |
| Adding new edit | 150 | 75 | 0 | 0 |
| Changing reports | 250 | 100 | 0 | 0 |
| Changes to CPT | 150 | 0 | 0 | 0 |
| Changes to Web publishing | 150 | 0 | 0 | 0 |
| Changes to OGOR/PASR form | 150 | 100 | 100 | 50 |
| Total hours | 1,050 | 375 | 200 | 100 |
| Average hourly rate | × $235 | × $235 | × $100 | × $75 |
| Cost per entity [Total hours × Average hourly rate] | $246,750 | $88,125 | $20,000 | $7,500 |
| Number of Businesses | N/A | × 32 | × 58 | × 115 |
| Total cost | | $2,820,000 | $1,160,000 | $862,500 |
| Industry Grand Total | | | | $4,842,500 |

The table below lists the overall estimated first year economic impact to Industry from the changes, based on the mid-range estimate of costs:

| Description | Annual (cost)/ benefit amount |
|---|---|
| Cost—Major Portion Royalty | ($20,000,000) |
| Cost—System Changes | ($4,842,500) |
| Net First Year Cost to Industry | ($24,842,500) |

After the first year, we anticipate that the estimated cost to Industry will be approximately $20,000,000 each year, based on 2012 data.

B. Indian Lessors

The impact to Indian lessors will be a net overall increase in royalties as a result of this change. This royalty increase will equal the royalty increase from Industry, or $20 million.

C. Federal Government

Cost—System Changes To Accommodate Reporting of Crude Oil Type

The Federal Government will incur system costs to accommodate crude oil type reporting similar to Industry. As detailed above, ONRR estimates that it will take 1,050 hours to implement system changes related to this rule, equating to a total cost of $246,750.

This rule will have no impact on Federal royalties. We also believe that there will be no administrative cost increases to the Federal Government because administrative savings due to decreased audit and litigation costs will offset the additional work needed to monitor and adjust the LCTD and IBMP value.

D. Summary of Royalty Impacts and Costs to Industry, Indian Lessors, and the Federal Government

In the table below, the negative values in the Industry column represent their estimated royalty and cost increases, while the positive values in the other columns represent the increase in Indian royalty receipts. For the purposes of this summary table, we assumed that the average for royalty increases is the midpoint of our range.

SUMMARY OF COSTS & ROYALTIES THE FIRST YEAR

| | Industry | Indian | Federal Government |
|---|---|---|---|
| Annual Additional Royalties Paid | ($20,000,000) | $0 | $0 |

SUMMARY OF COSTS & ROYALTIES THE FIRST YEAR—Continued

| | Industry | Indian | Federal Government |
|---|---|---|---|
| Cost to Modify Systems | ($4,842,500) | $0 | ($246,750) |
| Additional Royalties Received | $0 | $20,000,000 | $0 |
| Total | ($24,842,500) | $20,000,000 | ($246,750) |

After the first year, this rule will cost industry approximately $20 million per year in additional royalties paid, and Indian lessors will increase their annual royalty receipts by approximately $20 million. The Federal Government will not incur any additional costs after the first year.

*2. Regulatory Planning and Review (Executive Orders 12866 and 13563)*

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

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

*3. Regulatory Flexibility Act*

The Department of the Interior (Department) certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This rule will affect lessees under Indian mineral leases (excluding Osage Indian leases in Oklahoma). Lessees of Federal and Indian mineral leases are generally companies classified under the North American Industry Classification System (NAICS) Code 211111, which includes companies that extract crude petroleum and natural gas. For this NAICS code classification, a small company is one with fewer than 500 employees. Approximately 205 different companies submit royalty and production reports from Indian leases to ONRR each month. In addition, approximately 32 companies are large businesses under the U.S. Small Business Administration definition because they have over 500 employees. The Department believes that the remaining 173 companies affected by this rule are small businesses.

As provided in *1A Industry* of the *Procedural Matters* section, we believe that industry will incur a one-time cost to comply with this rule. On average, ONRR estimates that each small business will incur a one-time cost of between $7,500 and $20,000 to modify their systems to comply with this rule.

As we stated earlier, we believe, based on 2012 Indian oil sales, this rule will cost industry approximately $20 million dollars per year. Small businesses only accounted for 13.55 percent of the oil volumes sold in 2012. Applying that percentage to industry costs, ONRR estimates that the major portion provision will cost all small-business lessors approximately $2,710,000 per year. The amount will vary for each company depending on the volume of production that each small business produces and sells each year. We believe that reduced administrative costs, such as reduced accounting, auditing, and litigation expenses, will offset some of these costs.

In sum, we do not believe that this rule will result in a significant economic effect on a substantial number of small entities because (1) the initial one-time cost to a small business to modify its system will be between $7,500 and $20,000, and (2) this rule will cost the small businesses a collective total of $2,710,000 per year. Therefore, a Regulatory Flexibility Analysis will not be required, and, accordingly, a Small Entity Compliance Guide will not be required.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and ten Regional Fairness Boards receive comments from small businesses about Federal agency enforcement actions. The Ombudsman annually evaluates the enforcement activities and rates each agency's responsiveness to small business. If you wish to comment on the actions of ONRR, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

*4. Small Business Regulatory Enforcement Fairness Act (SBREFA)*

This rulemaking is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rulemaking:

a. Does not have an annual effect on the economy of $100 million or more. The effect will be limited to a maximum estimated at $2,710,000, which equals the $20,000,000 yearly cost of this rule to industry at large multiplied by 13.55 percent (volumes sold attributable to small businesses).

b. Does not cause a major increase in costs or prices for consumers; individual industries; Federal, State, Indian, or local government agencies; or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

*5. Unfunded Mandates Reform Act*

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. This rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. We are not required to provide a statement containing the information that the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) requires because this rule is not an unfunded mandate.

*6. Takings (E.O. 12630)*

Under the criteria in section 2 of E.O. 12630, this rule does not have any significant takings implications. This rule will not impose conditions or limitations on the use of any private property. Therefore, this rule does not

require a Takings Implication Assessment.

*7. Federalism (E.O. 13132)*

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. This rule does not substantially and directly affect the relationship between the Federal and State governments. The management of Indian leases is the responsibility of the Secretary of the Interior, and ONRR distributes all of the royalties that it collects from Indian leases to Tribes and individual Indian mineral owners. Because this rule does not alter that relationship, this rule does not require a Federalism summary impact statement.

*8. Civil Justice Reform (E.O. 12988)*

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

a. Meets the criteria of section 3(a), which requires that we review all regulations to eliminate errors and ambiguity and write them to minimize litigation.

b. Meets the criteria of section 3(b)(2), which requires that we write all regulations in clear language using clear legal standards.

*9. Consultation With Indian Tribal Governments (E.O. 13175)*

The Department strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. Under the Department's consultation policy and the criteria in E.O. 13175, we evaluated this rule and determined that it has no Tribal implications that will impose substantial, direct compliance costs on Indian Tribal governments.

Prior to formally promulgating this rule and throughout this rulemaking, ONRR has consulted with Tribes and representatives of individual Indian mineral owners as collaborative partners. On December 1, 2011, the Secretary signed the charter of the Indian Oil Valuation Negotiated Rulemaking Committee (Committee) and authorized the Committee under the Federal Advisory Committee Act. Members of the Committee included the Shoshone and Arapaho Tribes, Land Owners Association (Fort Berthold), Navajo Nation, Oklahoma Indian Land/Mineral Owners of Associated Nations, Ute Indian Tribe, Jicarilla Apache Nation, Blackfeet Nation and individual Indian mineral owner associations. The Committee engaged in substantive discussions under the Department's consultation policy; engaging in negotiated rulemaking is an appropriate process to engage in Tribal consultation.

Also, under this consultation policy and Executive Order criteria with Indian Tribes and individual Indian mineral owners on all policy changes that may affect them, ONRR scheduled public meetings in five different locations for the purpose of consulting with Indian Tribes and individual Indian mineral owners and to obtain public comments from other interested parties.

ONRR held consultation sessions with Tribes and individual Indian mineral owners on October 29, 2013, at the Civic Center in New Town, North Dakota; November 6, 2013, at Ft. Washakie, Wyoming; December 14, 2013, at the Wes Watkins Technology Center at Wetumka, Oklahoma; March 19–20, 2014, at the Indian Pueblo Cultural Center in Albuquerque, New Mexico; and March 31, 2014, at the BIA Agency in Ft. Duchene, Utah.

*10. Paperwork Reduction Act of 1995*

This rule:

(1) Does not contain any new information collection requirements.

(2) Does not require a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

This rule will modify § 1210.61 to require a lessee of Indian leases to report additional product codes for crude oil types on Form ONRR–2014. Currently, OMB approved a total of 239,937 burden hours for lessees to file their Forms ONRR–2014 under OMB Control Number 1012–0004. ONRR estimates that there will be no additional burden hours, beyond the initial hours that industry must incur in order to modify systems so as to accommodate this rule, to report the applicable crude oil type in the product code field.

This rule also changes the form filing requirements necessary to claim a transportation allowance for oil produced from Indian leases. Currently, OMB approved a total of 220 burden hours for lessees to file their Forms ONRR–4110 under OMB Control Number 1012–0002. ONRR estimates that there will be no additional burden hours because this rule will insignificantly reduce the burden hours associated with the Oil Transportation Allowance Report (Form ONRR–4110) under OMB Control Number 1012–0002. Rather than submitting estimated transportation cost information on the form and then following up with actual cost information at the end of the reporting cycle, the rule will require only responses with actual cost information. Also, under this rule, Indian lessees that have arm's-length transportation costs will no longer submit a Form ONRR–4110 to ONRR but will, instead, submit copies of the actual contracts to ONRR.

*11. National Environmental Policy Act*

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. We are not required to provide a detailed statement under the National Environmental Policy Act of 1969 (NEPA) because this rule qualifies for categorical exclusion under 43 CFR 46.210(c) and (i) and the DOI Departmental Manual, part 516, section 15.4.D: ''*(c) Routine financial transactions including such things as . . . audits, fees, bonds, and royalties . . . (i) Policies, directives, regulations, and guidelines: That are of an administrative, financial, legal, technical, or procedural nature.*'' We have also determined that this rule is not involved in any of the extraordinary circumstances listed in 43 CFR 46.215 that require further analysis under NEPA. The procedural changes resulting from the IBMP value would have no consequence on the physical environment. This rule does not alter, in any material way, natural resources exploration, production, or transportation.

*12. Effects on the Nation's Energy Supply (E.O. 13211)*

This rule is not a significant energy action under the definition in E.O. 13211. and, therefore, a Statement of Energy Effects is not required.

**List of Subjects**

*30 CFR Part 1206*

Coal, Continental shelf, Geothermal energy, Government contracts, Indians—lands, Mineral royalties, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements.

*30 CFR Part 1210*

Continental shelf, Geothermal energy, Government contracts, Indian leases, Indians—lands, Mineral royalties, Oil and gas reporting, Phosphate, Potassium, Reporting and recordkeeping requirements, Royalties, Sales contracts, Sales summary, Sodium, Solid minerals, Sulfur.

Dated: March 26, 2015.

**Kristen J. Sarri,**

*Principal Deputy Assistant Secretary for Policy, Management and Budget.*

## Authority and Issuance

For the reasons discussed in the preamble, ONRR amends 30 CFR parts 1206 and 1210 as follows:

## PART 1206—PRODUCT VALUATION

■ 1. The authority for part 1206 continues to read as follows:

**Authority:** 5 U.S.C. 301 *et seq.;* 25 U.S.C. 396 *et seq.,* 396a *et seq.,* 2101 *et seq.;* 30 U.S.C. 181 *et seq.,* 351 *et seq.,* 1001 *et seq.,* 1701 *et seq.;* 31 U.S.C. 9701; 43 U.S.C. 1301 *et seq.,* 1331 *et seq.,* and 1801 *et seq.*

■ 2. Revise subpart B of part 1206 to read as follows:

### Subpart B—Indian Oil

Sec.
1206.50 What is the purpose of this subpart?
1206.51 What definitions apply to this subpart?
1206.52 How do I calculate royalty value for oil that I or my affiliate sell(s) or exchange(s) under an arm's-length contract?
1206.53 How do I calculate royalty value for oil that I or my affiliate do(es) not sell under an arm's-length contract?
1206.54 How do I fulfill the lease provision regarding valuing production on the basis of the major portion of like-quality oil?
1206.55 What are my responsibilities to place production into marketable condition and to market production?
1206.56 What general transportation allowance requirements apply to me?
1206.57 How do I determine a transportation allowance if I have an arm's-length transportation contract?
1206.58 How do I determine a transportation allowance if I have a non-arm's-length transportation contract or have no contract?
1206.59 What interest applies if I improperly report a transportation allowance?
1206.60 What reporting adjustments must I make for transportation allowances?
1206.61 How will ONRR determine if my royalty payments are correct?
1206.62 How do I request a value determination?
1206.63 How do I determine royalty quantity and quality?
1206.64 What records must I keep to support my calculations of value under this subpart?
1206.65 Does ONRR protect information I provide?

## Subpart B—Indian Oil

### § 1206.50 What is the purpose of this subpart?

(a) This subpart applies to all oil produced from Indian (Tribal and allotted) oil and gas leases (except leases on the Osage Indian Reservation, Osage County, Oklahoma). This subpart does not apply to Federal leases, including Federal leases for which revenues are shared with Alaska Native Corporations. This subpart:

(1) Explains how you as a lessee must calculate the value of production for royalty purposes consistent with Indian mineral leasing laws, other applicable laws, and lease terms.

(2) Ensures the United States discharges its trust responsibilities for administering Indian oil and gas leases under the governing Indian mineral leasing laws, treaties, and lease terms.

(b) If you dispose of or report production on behalf of a lessee, the terms ''you'' and ''your'' in this subpart refer to you and not to the lessee. In this circumstance, you must determine and report royalty value for the lessee's oil by applying the rules in this subpart to your disposition of the lessee's oil.

(c) If the regulations in this subpart are inconsistent with:

(1) A Federal statute;

(2) A settlement agreement between the United States, Indian lessor, and a lessee resulting from administrative or judicial litigation;

(3) A written agreement between the Indian lessor, lessee, and the ONRR Director establishing a method to determine the value of production from any lease that ONRR expects at least would approximate the value established under this subpart; or

(4) An express provision of an oil and gas lease subject to this subpart then the statute, settlement agreement, written agreement, or lease provision will govern to the extent of the inconsistency.

(d) ONRR or Indian Tribes, which have a cooperative agreement with ONRR to audit under 30 U.S.C. 1732, may audit, or perform other compliance reviews, and require a lessee to adjust royalty payments and reports.

### § 1206.51 What definitions apply to this subpart?

For purposes of this subpart:

*Affiliate* means a person who controls, is controlled by, or is under common control with another person.

(1) Ownership or common ownership of more than 50 percent of the voting securities, or instruments of ownership, or other forms of ownership, of another person constitutes control. Ownership of less than 10 percent constitutes a presumption of non-control that ONRR may rebut.

(2) If there is ownership or common ownership of 10 through 50 percent of the voting securities or instruments of ownership, or other forms of ownership, of another person, ONRR will consider the following factors in determining whether there is control in a particular case:

(i) The extent to which there are common officers or directors;

(ii) With respect to the voting securities, or instruments of ownership, or other forms of ownership:

(A) The percentage of ownership or common ownership;

(B) The relative percentage of ownership or common ownership compared to the percentage(s) of ownership by other persons;

(C) Whether a person is the greatest single owner; and

(D) Whether there is an opposing voting bloc of greater ownership;

(iii) Operation of a lease, plant, or other facility;

(iv) The extent of participation by other owners in operations and day-to-day management of a lease, plant, or other facility; and

(v) Other evidence of power to exercise control over or common control with another person.

(3) Regardless of any percentage of ownership or common ownership, relatives, either by blood or marriage, are affiliates.

*Area* means a geographic region at least as large as the defined limits of an oil and/or gas field in which oil and/or gas lease products have similar quality, economic, and legal characteristics.

*Arm's-length contract* means a contract or agreement between independent persons who are not affiliates and who have opposing economic interests regarding that contract. To be considered arm's-length for any production month, a contract must satisfy this definition for that month, as well as when the contract was executed.

*Audit* means a review, conducted under the generally accepted *Governmental Auditing Standards,* of royalty reporting and payment activities of lessees, designees, or other persons who pay royalties, rents, or bonuses on Indian leases.

*BLM* means the Bureau of Land Management of the Department of the Interior.

*Condensate* means liquid hydrocarbons (generally exceeding 40 degrees of API gravity) recovered at the surface without resorting to processing. Condensate is the mixture of liquid hydrocarbons that results from condensation of petroleum hydrocarbons existing initially in a gaseous phase in an underground reservoir.

*Contract* means any oral or written agreement, including amendments or

revisions thereto, between two or more persons and enforceable by law that with due consideration creates an obligation.

*Designated area* means an area that ONRR designates for purposes of calculating Location and Crude Type Differentials applied to an IBMP value. ONRR will post designated areas on our Web site at *www.onrr.gov.* ONRR will monitor the market activity in the designated areas and, if necessary, hold a technical conference to review, modify, or add a particular designated area. ONRR will post any change to the designated areas on our Web site at *www.onrr.gov.* Criteria to determine any future changes to designated areas include, but are not limited to: Markets served, examples include refineries and/or market centers, such as Cushing, OK; access to markets, examples include access to similar infrastructure, such as pipelines, rail lines, and trucking; and/or similar geography, examples include no challenging geographical divides, large rivers, and/or mountains.

*Exchange agreement* means an agreement where one person agrees to deliver oil to another person at a specified location in exchange for oil deliveries at another location, as well as other consideration(s). Exchange agreements:

(1) May or may not specify prices for the oil involved;

(2) Frequently specify dollar amounts reflecting location, quality, or other differentials;

(3) Include buy/sell agreements, which specify prices to be paid at each exchange point and may appear to be two separate sales within the same agreement or in separate agreements; and

(4) May include, but are not limited to, exchanges of produced oil for specific types of oil (*e.g.* WTI); exchanges of produced oil for other oil at other locations (location trades); exchanges of produced oil for other grades of oil (grade trades); and multi-party exchanges.

*Field* means a geographic region situated over one or more subsurface oil and gas reservoirs encompassing at least the outermost boundaries of all oil and gas accumulations known to be within those reservoirs vertically projected to the land surface. Onshore fields usually are given names, and their official boundaries are often designated by oil and gas regulatory agencies in the respective States in which the fields are located.

*Gathering* means the movement of lease production to a central accumulation or treatment point on the lease, unit, or communitized area or to a central accumulation or treatment point off of the lease, unit, or communitized area, as BLM operations personnel approve.

*Gross proceeds* means the total monies and other consideration accruing for the disposition of oil produced. Gross proceeds also include, but are not limited to, the following examples:

(1) Payments for services, such as dehydration, marketing, measurement, or gathering that the lessee must perform—at no cost to the lessor—in order to put the production into marketable condition;

(2) The value of services to put the production into marketable condition, such as salt water disposal, that the lessee normally performs but that the buyer performs on the lessee's behalf

(3) Reimbursements for harboring or terminalling fees;

(4) Tax reimbursements, even though the Indian royalty interest may be exempt from taxation;

(5) Payments made to reduce or buy down the purchase price of oil to be produced in later periods by allocating those payments over the production whose price the payment reduces and including the allocated amounts as proceeds for the production as it occurs; and

(6) Monies and all other consideration to which a seller is contractually or legally entitled but does not seek to collect through reasonable efforts.

*IBMP* means the Index-Based Major Portion value calculated under § 1206.54.

*Indian Tribe* means any Indian Tribe, band, nation, pueblo, community, rancheria, colony, or other group of Indians for which any minerals or interest in minerals is held in trust by the United States or that is subject to Federal restriction against alienation.

*Individual Indian mineral owner* means any Indian for whom minerals or an interest in minerals is held in trust by the United States or who holds title subject to Federal restriction against alienation.

*Lease* means any contract, profit-share arrangement, joint venture, or other agreement issued or approved by the United States under an Indian mineral leasing law that authorizes exploration for, development or extraction of, or removal of lease products. Depending on the context, lease may also refer to the land area that the authorization covers.

*Lease products* means any leased minerals attributable to, originating from, or allocated to Indian leases.

*Lessee* means any person to whom the United States, a Tribe, or individual Indian mineral owner issues a lease and any person who has been assigned an obligation to make royalty or other payments required by the lease. Lessee includes:

(1) Any person who has an interest in a lease (including operating rights owners).

(2) An operator, purchaser, or other person with no lease interest who reports and/or makes royalty payments to ONRR or the lessor on the lessee's behalf.

*Lessor* means an Indian Tribe or individual Indian mineral owner who has entered into a lease.

*Like-quality oil* means oil that has similar chemical and physical characteristics.

*Location and Crude Type Differential* (*LCTD)* means the difference in value between the NYMEX Calendar Monthly Average (CMA) and the value that approximates the monthly Major Portion Price for any given month, designated area, and crude oil type.

*Location differential* means an amount paid or received (whether in money or in barrels of oil) under an exchange agreement that results from differences in location between oil delivered in exchange and oil received in the exchange. A location differential may represent all or part of the difference between the price received for oil delivered and the price paid for oil received under a buy/sell exchange agreement.

*Major Portion Price* means the highest price paid or offered at the time of production for the major portion of oil produced from the same designated area for the same crude oil type.

*Marketable condition* means lease products that are sufficiently free from impurities and otherwise in a condition that they will be accepted by a purchaser under a sales contract typical for the field or area.

*Net* means to reduce the reported sales value to account for transportation instead of reporting a transportation allowance as a separate entry on Form ONRR–2014.

*NYMEX Calendar Month Average Price* means the average of the New York Mercantile Exchange (NYMEX) daily settlement prices for light sweet oil delivered at Cushing, Oklahoma, calculated as follows:

(1) Sum the prices published for each day during the calendar month of production (excluding weekends and holidays) for oil to be delivered in the nearest month of delivery for which NYMEX futures prices are published corresponding to each such day.

(2) Divide the sum by the number of days on which those prices are

published (excluding weekends and holidays).

*Oil* means a mixture of hydrocarbons that existed in the liquid phase in natural underground reservoirs and remains liquid at atmospheric pressure after passing through surface separating facilities and is marketed or used as such. Condensate recovered in lease separators or field facilities is considered to be oil.

*ONRR* means the Office of Natural Resources Revenue of the Department of the Interior.

*Operating rights owner,* also known as a working interest owner, means any person who owns operating rights in a lease subject to this subpart. A record title owner is the owner of operating rights under a lease until the operating rights have been transferred from record title (see Bureau of Land Management regulations at 43 CFR 3100.0–5(d)).

*Person* means any individual, firm, corporation, association, partnership, consortium, or joint venture (when established as a separate entity).

*Processing* means any process designed to remove elements or compounds (hydrocarbon and non-hydrocarbon) from gas, including absorption, adsorption, or refrigeration. Field processes that normally take place on or near the lease, such as natural pressure reduction, mechanical separation, heating, cooling, dehydration, and compression, are not considered processing. The changing of pressures and/or temperatures in a reservoir is not considered processing.

*Prompt month* means the nearest month of delivery for which NYMEX futures prices are published during the trading month.

*Quality differential* means an amount paid or received under an exchange agreement (whether in money or in barrels of oil) that results from differences in API gravity, sulfur content, viscosity, metals content, and other quality factors between oil delivered and oil received in the exchange. A quality differential may represent all or part of the difference between the price received for oil delivered and the price paid for oil received under a buy/sell agreement.

*Roll* means an adjustment to the NYMEX price that is calculated as follows: Roll = $.6667 \times (P_0 - P_1) + .3333 \times (P_0 - P_2)$, where: $P_0$ = the average of the daily NYMEX settlement prices for deliveries during the prompt month that is the same as the month of production, as published for each day during the trading month for which the month of production is the prompt month; $P_1$ = the average of the daily NYMEX settlement prices for deliveries during the month following the month of production, published for each day during the trading month for which the month of production is the prompt month; and $P_2$ = the average of the daily NYMEX settlement prices for deliveries during the second month following the month of production, as published for each day during the trading month for which the month of production is the prompt month. Calculate the average of the daily NYMEX settlement prices using only the days on which such prices are published (excluding weekends and holidays). ONRR reserves the option of terminating the use of the roll when ONRR believes that the roll is no longer a common industry practice. ONRR also retains the option to redefine how to calculate the roll to comport with changes in industry practice. To terminate or otherwise redefine how to calculate the roll, ONRR will explain its rationale for terminating or redefining how to calculate the roll by publishing a notice in the **Federal Register**, to provide an opportunity for comment.

(1) *Example 1: Prices in out months are lower going forward.* The month of production for which you must determine royalty value is December 2012. December was the prompt month from October 23 through November 20. January was the first month following the month of production, and February was the second month following the month of production. $P_0$, therefore, is the average of the daily NYMEX settlement prices for deliveries during December published for each business day between October 23 and November 20. $P_1$ is the average of the daily NYMEX settlement prices for deliveries during January published for each business day between October 23 and November 20. $P_2$ is the average of the daily NYMEX settlement prices for deliveries during February published for each business day between October 23 and November 20. In this example, assume that $P_0$ = \$95.08 per bbl; $P_1$ = \$95.03 per bbl; and $P_2$ = \$94.93 per bbl. In this example (a declining market), Roll = $.6667 \times (\$95.08 - \$95.03) + .3333 \times (\$95.08 - \$94.93) = \$0.03 + \$0.05 = \$0.08$. You add this number to the NYMEX price.

(2) *Example 2: Prices in out months are higher going forward.* The month of production for which you must determine royalty value is November 2012. November was the prompt month from September 21 through October 22. December was the first month following the month of production, and January was the second month following the month of production. $P_0$, therefore, is the average of the daily NYMEX settlement prices for deliveries during November published for each business day between September 21 and October 22. $P_1$ is the average of the daily NYMEX settlement prices for deliveries during December published for each business day between September 21 and October 22. $P_2$ is the average of the daily NYMEX settlement prices for deliveries during January published for each business day between September 21 and October 22. In this example, assume that $P_0$ = \$91.28 per bbl; $P_1$ = \$91.65 per bbl; and $P_2$ = \$92.10 per bbl. In this example (a rising market), Roll = $.6667 \times (\$91.28 - \$91.65) + .3333 \times (\$91.28 - \$92.10) = (-\$0.25) + (-\$0.27) = (-\$0.52)$. You add this negative number to the NYMEX price (effectively a subtraction from the NYMEX price).

*Sale* means a contract between two persons where:

(1) The seller unconditionally transfers title to the oil to the buyer and does not retain any related rights, such as the right to buy back similar quantities of oil from the buyer elsewhere.

(2) The buyer pays money or other consideration for the oil.

(3) The parties' intent is for a sale of the oil to occur.

*Sales type code* means the contract type or general disposition (*e.g.* arm's-length or non-arm's-length) of production from the lease. The sales type code applies to the sales contract, or other disposition, and not to the arm's-length or non-arm's-length nature of a transportation allowance.

*Trading month* means the period extending from the second business day before the 25th day of the second calendar month preceding the delivery month (or, if the 25th day of that month is a non-business day, the second business day before the last business day preceding the 25th day of that month) through the third business day before the 25th day of the calendar month preceding the delivery month (or, if the 25th day of that month is a non-business day, the third business day before the last business day preceding the 25th day of that month), unless the NYMEX publishes a different definition or different dates on its official Web site, *www.nymex.com,* in which case, the NYMEX definition will apply.

*Transportation allowance* means a deduction in determining royalty value for the reasonable, actual costs of moving oil to a point of sale or delivery off of the lease, unit area, or communitized area. The transportation allowance does not include gathering costs.

*WTI* means West Texas Intermediate.

*You* means a lessee, operator, or other person who pays royalties under this subpart.

**§ 1206.52 How do I calculate royalty value for oil that I or my affiliate sell(s) or exchange(s) under an arm's-length contract?**

(a) The value of production for royalty purposes for your lease is the higher of either the value determined under this section or the IBMP value calculated under § 1206.54. The value of oil under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the arm's-length contract, less applicable allowances determined under § 1206.56 or § 1206.57. You must use this paragraph (a) to value oil when:

(1) You sell under an arm's-length sales contract.

(2) You sell or transfer to your affiliate or another person under a non-arm's-length contract and that affiliate or person, or another affiliate of either of them, then sells the oil under an arm's-length contract.

(b) If you have multiple arm's-length contracts to sell oil produced from a lease that is valued under paragraph (a) of this section, the value of the oil is the higher of the volume-weighted average of the values established under this section for all contracts for the sale of oil produced from that lease or the IBMP value calculated under § 1206.54.

(c) If ONRR determines that the gross proceeds accruing to you or your affiliate does not reflect the reasonable value of the production due to either:

(1) Misconduct by or between the parties to the arm's-length contract; or

(2) Breach of your duty to market the oil for the mutual benefit of yourself and the lessor, ONRR will establish a value based on other relevant matters.

(i) ONRR will not use this provision to simply substitute its judgment of the market value of the oil for the proceeds received by the seller under an arm's-length sales contract.

(ii) The fact that the price received by the seller under an arm's-length contract is less than other measures of market price is insufficient to establish breach of the duty to market unless ONRR finds additional evidence that the seller acted unreasonably or in bad faith in the sale of oil produced from the lease.

(d) You have the burden of demonstrating that your or your affiliate's contract is arm's-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate's contract include all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the oil.

(f) You must base value on the highest price that you or your affiliate can receive through legally enforceable claims under the oil sales contract.

(1) Absent contract revision or amendment, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate make timely application for a price increase or benefit allowed under your or your affiliate's contract—but the purchaser refuses—and you or your affiliate take reasonable documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional monies or consideration resulting from the price increase. You may not construe this paragraph (f)(2) to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay, in whole or in part, or in a timely manner, for a quantity of oil.

(g)(1) You or your affiliate must make all contracts, contract revisions, or amendments in writing, and all parties to the contract must sign the contract, contract revisions, or amendments.

(2) This provision applies notwithstanding any other provisions in this title 30 of the *Code of Federal Regulations* to the contrary.

(h) If you or your affiliate enter(s) into an arm's-length exchange agreement, or multiple sequential arm's-length exchange agreements, then you must value your oil under this paragraph (h).

(1) If you or your affiliate exchange(s) oil at arm's length for WTI or equivalent oil at Cushing, Oklahoma, you must value the oil using the NYMEX price, adjusted for applicable location and quality differentials under paragraph (h)(3) of this section and any transportation costs under paragraph (h)(4) of this section and §§ 1206.56 and 1206.57 or § 1206.58.

(2) If you do not exchange oil for WTI or equivalent oil at Cushing, but exchange it at arm's length for oil at another location and following the arm's-length exchange(s) you or your affiliate sell(s) the oil received in the exchange(s) under an arm's-length contract, then you must use the gross proceeds under your or your affiliate's arm's-length sales contract after the exchange(s) occur(s), adjusted for applicable location and quality differentials under paragraph (h)(3) of this section and any transportation costs under paragraph (h)(4) of this section and §§ 1206.56 and 1206.57 or § 1206.58.

(3) You must adjust your gross proceeds for any location or quality differential, or other adjustments, that you received or paid under the arm's-length exchange agreement(s). If ONRR determines that any exchange agreement does not reflect reasonable location or quality differentials, ONRR may adjust the differentials that you used based on relevant information. You may not otherwise use the price or differential specified in an arm's-length exchange agreement to value your production.

(4) If you value oil under this paragraph (h), ONRR will allow a deduction, under §§ 1206.56 and 1206.57 or § 1206.58, for the reasonable, actual costs to transport the oil:

(i) From the lease to a point where oil is given in exchange.

(ii) If oil is not exchanged to Cushing, Oklahoma, from the point where oil is received in exchange to the point where the oil received in exchange is sold.

(5) If you or your affiliate exchange(s) your oil at arm's length, and neither paragraph (h)(1) nor (2) of this section applies, ONRR will establish a value for the oil based on relevant matters. After ONRR establishes the value, you must report and pay royalties and any late payment interest owed based on that value.

**§ 1206.53 How do I calculate royalty value for oil that I or my affiliate do(es) not sell under an arm's-length contract?**

(a) The value of production for royalty purposes for your lease is the higher of either the value determined under this section or the IBMP value calculated under § 1206.54. The unit value of your oil not sold under an arm's-length contract under this section for royalty purposes is the volume-weighted average of the gross proceeds paid or received by you or your affiliate, including your refining affiliate, for purchases or sales under arm's-length contracts.

(1) When calculating that unit value, use only purchases or sales of other like-quality oil produced from the field (or the same area if you do not have sufficient arm's-length purchases or sales of oil produced from the field) during the production month.

(2) You may adjust the gross proceeds determined under paragraph (a) of this section for transportation costs under paragraph (c) of this section and §§ 1206.56 and 1206.57 or § 1206.58 before including those proceeds in the volume-weighted average calculation.

(3) If you have purchases away from the field(s) and cannot calculate a price in the field because you cannot determine the seller's cost of transportation that would be allowed under paragraph (c) of this section and § 1206.56 and § 1206.57 or § 1206.58,

you must not include those purchases in your volume-weighted average calculation.

(b) Before calculating the volume-weighted average, you must normalize the quality of the oil in your or your affiliate's arm's-length purchases or sales to the same gravity as that of the oil produced from the lease. Use applicable gravity adjustment tables for the field (or the same general area for like-quality oil if you do not have gravity adjustment tables for the specific field) to normalize for gravity, as shown in the example below.

(1) *Example 1.* Assume that a lessee, who owns a refinery and refines the oil produced from the lease at that refinery, purchases like-quality oil from other producers in the same field at arm's length for use as feedstock in its refinery. Further assume that the oil produced from the lease that is being valued under this section is Wyoming general sour with an API gravity of 23.5°. Assume that the refinery purchases at arm's-length oil (all of which must be Wyoming general sour) in the following volumes of the API gravities stated at the prices and locations indicated:

| | | | |
|---|---|---|---|
| 10,000 bbl | 24.5° | $34.70/bbl | Purchased in the field. |
| 8,000 bbl | 24.0° | $34.00/bbl | Purchased at the refinery after the third-party producer transported it to the refinery, and the lessee does not know the transportation costs. |
| 9,000 bbl | 23.0° | $33.25/bbl | Purchased in the field. |
| 4,000 bbl | 22.0° | $33.00/bbl | Purchased in the field. |

(2) *Example 2.* Because the lessee does not know the costs that the seller of the 8,000 bbl incurred to transport that volume to the refinery, that volume will not be included in the volume-weighted average price calculation. Further assume that the gravity adjustment scale provides for a deduction of $0.02 per 1/10 degree API gravity below 34°. Normalized to 23.5° (the gravity of the oil being valued under this section), the prices of each of the volumes that the refiner purchased that are included in the volume-weighted average calculation are as follows:

| | | | |
|---|---|---|---|
| 10,000 bbl | 24.5° | $34.50/bbl | (1.0° difference over 23.5° = $0.20 deducted). |
| 9,000 bbl | 23.0° | $33.35/bbl | (0.5° difference under 23.5° = $0.10 added). |
| 4,000 bbl | 22.0° | $33.30/bbl | (1.5° difference under 23.5° = $0.30 added). |

(3) *Example 3.* The volume-weighted average price is ((10,000 bbl × $34.50/bbl) + (9,000 bbl × $33.35/bbl) + (4,000 bbl × $33.30/bbl)) / 23,000 bbl = $33.84/bbl. That price will be the value of the oil produced from the lease and refined prior to an arm's-length sale under this section.

(c) If you value oil under this section, ONRR will allow a deduction, under §§ 1206.56 and 1206.57 or § 1206.58, for the reasonable, actual costs:

(1) That you incur to transport oil that you or your affiliate sell(s), which is included in the volume-weighted average price calculation, from the lease to the point where the oil is sold.

(2) That the seller incurs to transport oil that you or your affiliate purchase(s), which is included in the volume-weighted average cost calculation, from the property where it is produced to the point where you or your affiliate purchase(s) it. You may not deduct any costs of gathering as part of a transportation deduction or allowance.

(d) If paragraphs (a) and (b) of this section result in an unreasonable value for your production as a result of circumstances regarding that production, ONRR's Director may establish an alternative valuation method.

**§ 1206.54 How do I fulfill the lease provision regarding valuing production on the basis of the major portion of like-quality oil?**

(a) This section applies to any Indian leases that contain a major portion provision for determining value for royalty purposes. This section also applies to any Indian leases that provide that the Secretary may establish value for royalty purposes. The value of production for royalty purposes for your lease is the higher of either the value determined under this section or the gross proceeds you calculated under § 1206.52 or § 1206.53.

(b) You must submit a monthly Form ONRR–2014 using the higher of the IBMP value determined under this section or your gross proceeds under § 1206.52 or § 1206.53. Your Form ONRR–2014 must meet the requirements of 30 CFR 1210.61.

(c) ONRR will determine the monthly IBMP value for each designated area and crude oil type and post those values on our Web site at *www.onrr.gov.* The monthly IBMP value by designated area and crude oil type is calculated as follows:

(1) For Indian leases located in Oklahoma:

$$\left[\left(\begin{matrix}\text{NYMEX CMA}\\ \text{Price}\end{matrix}\right) \text{+/- (Roll)}\right] \text{ x } (1 - \text{LCTD})$$

(2) For all other Indian leases:

$$\left(\begin{matrix}\text{NYMEX CMA}\\ \text{Price}\end{matrix}\right) \text{ x } (1\text{-LCTD})$$

(d) ONRR will calculate the initial LCTD for each designated area (the same designated areas posted on its Web site at *www.onrr.gov*) and crude oil type using the following formula:

$$\left[\frac{\text{(Average of Monthly NYMEX CMA for Previous 12 Months - Average of Monthly Major Portion Prices for Previous 12 Months)}}{\text{Average of Monthly NYMEX CMA for Previous 12 Months}}\right]$$

(1) For the first full production month after July 1, 2015, ONRR will calculate the monthly Major Portion Prices using data reported on the Form ONRR–2014 for the previous 12 production months prior to July 1, 2015 (Previous Twelve Months). To the extent that ONRR does not have data on the Form ONRR–2014 regarding the crude oil type for the entire previous twelve months, ONRR will assume the crude oil type is the same for those months for which ONRR does not have data as the months for which the crude oil type was reported on the Form ONRR–2014 for the same leases and/or agreements.

(i) ONRR will array the calculated prices net of transportation by month from highest to lowest price for each designated area and crude oil type. For each month, ONRR will calculate the Major Portion Price as that price at which 25 percent plus 1 barrel (by volume) of the oil (starting from the highest) is sold.

(ii) To calculate the average of the monthly Major Portion Prices for the previous 12 months, ONRR will add the monthly Major Portion Prices calculated in paragraph (d)(1)(i) of this section and divide by 12.

(2) For every month following the first full production month after July 1, 2015, ONRR will monitor the LCTD using data reported on the Form ONRR–2014 for the month ending two months before the current production month.

(i) ONRR will use the oil sales volume that lessees report on Form ONRR–2014 to monitor and, if necessary, to modify the LCTD used in the IBMP value.

(ii) ONRR will monitor oil sales volumes not reported under the sales type code OINX, as provided in 30 CFR 1210.61(a) and (b), on the Form ONRR–2014 on a monthly basis by designated area and crude oil type.

(iii) If the monthly oil sales volumes not reported under the sales type code OINX varies more than +/− 3 percent from 25 percent of the total reported oil sales volume for the month, then ONRR will revise the LCTD prospectively starting with the following month.

(A) If monthly oil sales volumes not reported under the sales type code OINX on Form ONRR–2014 by the designated area and crude oil type fall below 22 percent, ONRR will increase the LCTD by 10 percent every month until the monthly oil sales volumes reported under the sales type code for gross proceeds on Form ONRR–2014 fall within the +/− 3 percent range. In Example 1, assume that the IBMP value is $81.06 and the LCTD for the designated area is 14.28 percent. In the table below, the Percent of Volume not reported as OINX is less than 22 percent, which triggers a modification to the LCTD. ONRR will adjust the LCTD upward by 10 percent (14.28 percent × 1.10). Therefore, for the next month, the LCTD will be 15.71 percent. In the following month, the IBMP value will equal the next month's NYMEX CMA multiplied by (1 − 0.1571). ONRR will continue to make adjustments in subsequent months until monthly sales volumes not reported as OINX fall within 22–28 percent of the total monthly sales volume.

EXAMPLE 1—DIFFERENTIAL ADJUSTMENT WHEN ARMS SALES VOLUME FOR THE CURRENT MONTH FALLS BELOW 22% OF TOTAL MONTHLY SALES VOLUME

| Lease | Sales volume | Unit price | Sales type code | Cumulative volume | Percent of volume |
|---|---|---|---|---|---|
| 1 | 220 | 81.95 | ARMS | 220 | 9.02 |
| 2 | 275 | 81.71 | ARMS | 495 | 20.29 |
| 3 | 400 | 81.06 | OINX | 895 | 36.68 |
| 4 | 425 | 81.06 | OINX | 1,320 | 54.10 |
| 5 | 370 | 81.06 | OINX | 1,690 | 69.26 |
| 6 | 400 | 81.06 | OINX | 2,090 | 85.66 |
| 7 | 350 | 81.06 | OINX | 2,440 | 100.00 |
| | 2,440 | | | | |

(B) If monthly oil sales volumes not reported under the sales type code OINX on Form ONRR–2014 by designated area and crude oil type exceed 28 percent, then ONRR will decrease the LCTD by 10 percent every month until the monthly oil sales volumes reported under the sales type code for gross proceeds on Form ONRR–2014 fall within the +/− 3 percent range. In Example 2, assume that the IBMP value is $81.06 and the LCTD is 14.28 percent. As noted in the table below, however, the Percent of Volume not reported as OINX is 32.69 percent, exceeding the 28 percent threshold, which triggers a modification to the LCTD. ONRR will adjust the LCTD downward by 10 percent (14.28 percent × 0.90). Therefore, for the next month, the LCTD will be 12.85 percent. In the following month, the IBMP will equal the next month's NYMEX CMA multiplied by (1 − 0.1285). ONRR will continue to make adjustments in subsequent months until monthly sales volumes reported as ARMS fall within 22–28 percent of the total monthly sales volume.

EXAMPLE 2—DIFFERENTIAL ADJUSTMENT WHEN ARMS SALES VOLUME NOT REPORTED AS OINX FOR THE CURRENT MONTH EXCEEDS 28% OF TOTAL MONTHLY SALES VOLUME

| Lease | Sales volume | Unit price | Sales type code | Cumulative volume | Percent of volume |
|---|---|---|---|---|---|
| 1 | 230 | 81.95 | ARMS | 230 | 11.06 |
| 2 | 275 | 81.71 | ARMS | 505 | 24.28 |
| 3 | 175 | 81.45 | ARMS | 680 | 32.69 |
| 4 | 250 | 81.06 | OINX | 930 | 44.71 |

EXAMPLE 2—DIFFERENTIAL ADJUSTMENT WHEN ARMS SALES VOLUME NOT REPORTED AS OINX FOR THE CURRENT MONTH EXCEEDS 28% OF TOTAL MONTHLY SALES VOLUME—Continued

| Lease | Sales volume | Unit price | Sales type code | Cumulative volume | Percent of volume |
|---|---|---|---|---|---|
| 5 | 425 | 81.06 | OINX | 1,355 | 65.14 |
| 6 | 325 | 81.06 | OINX | 1,680 | 80.77 |
| 7 | 400 | 81.06 | OINX | 2,080 | 100.00 |
| | 2,080 | | | | |

(e) In designated areas where there is insufficient data reported to ONRR on Form ONRR–2014 to determine a differential for a specific crude oil type, ONRR will use its discretion to determine an appropriate IBMP value.

**§ 1206.55 What are my responsibilities to place production into marketable condition and to market production?**

(a) You must place oil in marketable condition and market the oil for the mutual benefit of the lessee and the lessor at no cost to the Indian lessor unless the lease agreement provides otherwise.

(b) If you must use gross proceeds under an arm's-length contract or your affiliate's gross proceeds under an arm's-length exchange agreement to determine value under § 1206.52 or § 1206.53, you must increase those gross proceeds to the extent that the purchaser, or any other person, provides certain services that the seller normally would be responsible to perform in order to place the oil in marketable condition or to market the oil.

**§ 1206.56 What general transportation allowance requirements apply to me?**

(a) ONRR will allow a deduction for the reasonable, actual costs to transport oil from the lease to the point off of the lease under § 1206.52 or § 1206.53, as applicable. You may not deduct transportation costs to reduce royalties where you did not incur any costs to move a particular volume of oil. ONRR will not grant a transportation allowance for transporting oil taken as Royalty-In-Kind (RIK).

(b)(1) Except as provided in paragraph (b)(2) of this section, your transportation allowance deduction on the basis of a sales type code may not exceed 50 percent of the value of the oil at the point of sale, as determined under § 1206.52. Transportation costs cannot be transferred between sales type codes or to other products.

(2) Upon your request, ONRR may approve a transportation allowance deduction in excess of the limitation prescribed by paragraph (b)(1) of this section. You must demonstrate that the transportation costs incurred in excess of the limitation prescribed in paragraph (b)(1) of this section were reasonable, actual, and necessary. An application for exception (using Form ONRR–4393, Request to Exceed Regulatory Allowance Limitation) must contain all relevant and supporting documentation necessary for ONRR to make a determination. Under no circumstances may the value, for royalty purposes, under any sales type code, be reduced to zero.

(c) You must express transportation allowances for oil in dollars per barrel. If you or your affiliate's payments for transportation under a contract are not on a dollar-per-barrel basis, you must convert whatever consideration you or your affiliate are paid to a dollar-per-barrel equivalent.

(d) You must allocate transportation costs among all products produced and transported as provided in § 1206.57.

(e) All transportation allowances are subject to monitoring, review, audit, and adjustment.

(f) If, after a review or audit, ONRR determines you have improperly determined a transportation allowance authorized by this subpart, then you must pay any additional royalties due plus late payment interest calculated under § 1218.54 of this chapter or report a credit for, or request a refund of, any overpaid royalties without interest under § 1218.53 of this chapter.

(g) You may not deduct any costs of gathering as part of a transportation deduction or allowance.

**§ 1206.57 How do I determine a transportation allowance if I have an arm's-length transportation contract?**

(a) *Arm's-length transportation.* (1) If you incur transportation costs under an arm's-length contract, your transportation allowance is the reasonable, actual costs that you incur to transport oil under that contract. You have the burden of demonstrating that your contract is arm's-length.

(2) You must submit to ONRR a copy of your arm's-length transportation contract(s) and all subsequent amendments to the contract(s) within 2 months of the date that ONRR receives your report, which claims the allowance on Form ONRR–2014.

(3) If ONRR determines that the consideration paid under an arm's-length transportation contract does not reflect the reasonable value of the transportation because of misconduct by or between the contracting parties, or because the lessee otherwise has breached its duty to the lessor to market the production for the mutual benefit of the lessee and the lessor, then ONRR shall require that the transportation allowance be determined in accordance with paragraph (b) of this section. When ONRR determines that the value of the transportation may be unreasonable, ONRR will notify the lessee and give the lessee an opportunity to provide written information justifying the lessee's transportation costs.

(4)(i) If an arm's-length transportation contract includes more than one liquid product, and the transportation costs attributable to each product cannot be determined from the contract, then you must allocate the total transportation costs in a consistent and equitable manner to each of the liquid products transported in the same proportion as the ratio of the volume of each product (excluding waste products which have no value) to the volume of all liquid products (excluding waste products which have no value). Except as provided in this paragraph (a)(4)(i), you may not take an allowance for the costs of transporting lease production, which is not royalty-bearing, without ONRR's approval.

(ii) Notwithstanding the requirements of paragraph (a)(4)(i) of this section, you may propose to ONRR a cost allocation method on the basis of the values of the products transported. ONRR shall approve the method unless it determines that it is not consistent with the purposes of the regulations in this part.

(5) If an arm's-length transportation contract includes both gaseous and liquid products, and the transportation costs attributable to each product cannot be determined from the contract, you must propose an allocation procedure to ONRR.

(i) You may use the oil transportation allowance determined in accordance with its proposed allocation procedure

until ONRR issues its determination on the acceptability of the cost allocation.

(ii) You must submit to ONRR all available data to support your proposal.

(iii) You must submit your initial proposal within 3 months after the last day of the month for which you request a transportation allowance, whichever is later (unless ONRR approves a longer period).

(iv) ONRR will determine the oil transportation allowance based on your proposal and any additional information that ONRR deems necessary.

(6) Where an arm's-length sales contract price includes a provision whereby the listed price is reduced by a transportation factor, ONRR will not consider the transportation factor to be a transportation allowance. You may use the transportation factor to determine your gross proceeds for the sale of the product. The transportation factor may not exceed 50 percent of the base price of the product without ONRR's approval.

(b) *Reporting requirements.* (1) If ONRR requests, you must submit all data used to determine your transportation allowance. You must provide the data within a reasonable period of time that ONRR will determine.

(2) You must report transportation allowances as a separate entry on Form ONRR–2014. ONRR may approve a different reporting procedure on allotted leases and with lessor approval on Tribal leases.

(3) ONRR may establish, in appropriate circumstances, reporting requirements that are different from the requirements of this section.

**§ 1206.58 How do I determine a transportation allowance if I have a non-arm's-length transportation contract or have no contract?**

(a) *Non-arm's-length or no contract.* (1) If you have a non-arm's-length transportation contract or no contract, including those situations where you or your affiliate perform(s) transportation services for you, the transportation allowance is based on your reasonable, actual costs as provided in this paragraph (a)(1).

(2) You must submit the actual cost information to support the allowance to ONRR on Form ONRR–4110, Oil Transportation Allowance Report, within 3 months after the end of the calendar year to which the allowance applies. However, ONRR may approve a longer time period. ONRR will monitor the allowance deductions to ensure that deductions are reasonable and allowable. When necessary or appropriate, ONRR may require you to modify your actual transportation allowance deduction.

(3) You must base a transportation allowance for non-arm's-length or no-contract situations on your actual costs for transportation during the reporting period, including operating and maintenance expenses, overhead, and either depreciation and a return on undepreciated capital investment under paragraph (a)(3)(iv)(A) of this section, or a cost equal to the initial capital investment in the transportation system multiplied by a rate of return under paragraph (a)(3)(iv)(B) of this section. Allowable capital costs are generally those for depreciable fixed assets (including costs of delivery and installation of capital equipment), which are an integral part of the transportation system.

(i) Allowable operating expenses include: Operations supervision and engineering; operations labor; fuel; utilities; materials; ad valorem property taxes; rent; supplies; and any other directly allocable and attributable operating expense that the lessee can document.

(ii) Allowable maintenance expenses include: Maintenance of the transportation system; maintenance of equipment; maintenance labor; and other directly allocable and attributable maintenance expenses that the lessee can document.

(iii) Overhead directly attributable and allocable to the operation and maintenance of the transportation system is an allowable expense. State and Federal income taxes and severance taxes and other fees, including royalties, are not allowable expenses.

(iv) You may use either depreciation or a return on depreciable capital investment. After you have elected to use either method for a transportation system, you may not later elect to change to the other alternative without approval from ONRR.

(A) To compute depreciation, you may elect to use either a straight-line depreciation method, based on the life of equipment or on the life of the reserves, which the transportation system services, or on a unit-of-production method. After you make an election, you may not change methods without ONRR's approval. A change in ownership of a transportation system will not alter the depreciation schedule the original transporter/lessee established for the purposes of the allowance calculation. With or without a change in ownership, a transportation system can be depreciated only once. You may not depreciate equipment below a reasonable salvage value.

(B) ONRR will allow as a cost an amount equal to the initial capital investment in the transportation system multiplied by the rate of return determined under paragraph (a)(3)(v) of this section. No allowance will be provided for depreciation.

(v) The rate of return is the industrial rate associated with Standard and Poor's BBB rating. The rate of return you must use is the monthly average rate as published in Standard and Poor's Bond Guide for the first month of the reporting period for which the allowance is applicable and is effective during the reporting period. You must redetermine the rate at the beginning of each subsequent transportation allowance reporting period (which is determined under paragraph (b) of this section).

(4)(i) You must determine the deduction for transportation costs based on your or your affiliate's cost of transporting each product through each individual transportation system. Where more than one liquid product is transported, you must allocate costs to each of the liquid products transported in the same proportion as the ratio of the volume of each liquid product (excluding waste products which have no value) to the volume of all liquid products (excluding waste products which have no value) and you must make such allocation in a consistent and equitable manner. Except as provided in this paragraph (a)(4)(i), you may not take an allowance for transporting lease production that is not royalty-bearing without ONRR's approval.

(ii) Notwithstanding the requirements of paragraph (a)(4)(i) of this section, you may propose to ONRR a cost allocation method on the basis of the values of the products transported. ONRR will approve the method unless we determine that it is not consistent with the purposes of the regulations in this part.

(5) Where both gaseous and liquid products are transported through the same transportation system, you must propose a cost allocation procedure to ONRR.

(i) You may use the oil transportation allowance determined in accordance with its proposed allocation procedure until ONRR issues our determination on the acceptability of the cost allocation.

(ii) You must submit to ONRR all available data to support your proposal.

(iii) You must submit your initial proposal within 3 months after the last day of the month for which you request a transportation allowance (unless ONRR approves a longer period).

(iv) ONRR will determine the oil transportation allowance based on your

proposal and any additional information that ONRR deems necessary.

(6) You may apply to ONRR for an exception from the requirement that you compute actual costs under paragraphs (a)(1) through (5) of this section.

(i) ONRR will grant the exception only if you have a tariff for the transportation system the Federal Energy Regulatory Commission (FERC) has approved for Indian leases.

(ii) ONRR will deny the exception request if it determines that the tariff is excessive as compared to arm's-length transportation charges by pipelines, owned by the lessee or others, providing similar transportation services in that area.

(iii) If there are no arm's-length transportation charges, ONRR will deny the exception request if:

(A) No FERC cost analysis exists and the FERC has declined to investigate under ONRR timely objections upon filing.

(B) The tariff significantly exceeds the lessee's actual costs for transportation as determined under this section.

(b) *Reporting requirements.* (1) If ONRR requests, you must submit all data used to determine your transportation allowance. You must provide the data within a reasonable period of time that ONRR will determine.

(2) You must report transportation allowances as a separate entry on Form ONRR–2014. ONRR may approve a different reporting procedure on allotted leases and with lessor approval on Tribal leases.

(3) ONRR may require you to submit all of the data that you used to prepare your Form ONRR–4110. You must submit the data within a reasonable period of time that ONRR determines.

(4) ONRR may establish, in appropriate circumstances, reporting requirements that are different from the requirements of this section.

(5) If you are authorized to use your FERC-approved tariff as your transportation cost under paragraph (a)(6) of this section, you must follow the reporting requirements of § 1206.57(b).

(c) Notwithstanding any other provisions of this subpart, for other than arm's-length contracts, no cost will be allowed for oil transportation that results from payments (either volumetric or for value) for actual or theoretical losses. This section does not apply when the transportation allowance is based upon a FERC or State regulatory agency approved tariff.

(d) The provisions of this section will apply to determine transportation costs when establishing value using a netback valuation procedure or any other procedure that requires deduction of transportation costs.

**§ 1206.59 What interest applies if I improperly report a transportation allowance?**

(a) If you deduct a transportation allowance on Form ONRR–2014 without complying with the requirements of §§ 1206.56 and § 1206.57 or 1206.58, you must pay additional royalties due plus late payment interest calculated under § 1218.54 of this chapter.

(b) If you erroneously report a transportation allowance that results in an underpayment of royalties, you must pay any additional royalties due plus late payment interest calculated under § 1218.54 of this chapter.

**§ 1206.60 What reporting adjustments must I make for transportation allowances?**

(a) If your actual transportation allowance is less than the amount that you claimed on Form ONRR–2014 for each month during the allowance reporting period, you must pay additional royalties due, plus late payment interest calculated under § 1218.54 of this chapter from the first day of the first month that you were authorized to deduct a transportation allowance to the date that you repay the difference.

(b) If the actual transportation allowance is greater than the amount that you claimed on Form ONRR–2014 for any month during the period reported on the allowance form, you may report a credit for, or request a refund of, any overpaid royalties without interest under § 1218.53 of this chapter.

(c) If you make an adjustment under paragraph (a) or (b) of this section, then you must submit a corrected Form ONRR–2014 to reflect actual costs, together with any payment, using instructions that ONRR provides.

**§ 1206.61 How will ONRR determine if my royalty payments are correct?**

(a)(1) ONRR may monitor, review, and audit the royalties that you report, and, if ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR may direct you to use a different measure of royalty value.

(2) If ONRR directs you to use a different royalty value, you must pay any additional royalties due plus late payment interest calculated under § 1218.54 of this chapter, or you may report a credit for, or request a refund of, any overpaid royalties without interest under § 1218.53 of this chapter.

(b) When the provisions in this subpart refer to gross proceeds, in conducting reviews and audits, ONRR will examine if your or your affiliate's contract reflects the total consideration actually transferred, either directly or indirectly, from the buyer to you or your affiliate for the oil. If ONRR determines that a contract does not reflect the total consideration, you must value the oil sold as the total consideration accruing to you or your affiliate.

**§ 1206.62 How do I request a value determination?**

(a) You may request a value determination from ONRR regarding any oil produced. Your request must:

(1) Be in writing.

(2) Identify specifically all leases involved, all interest owners of those leases, the designee(s), and the operator(s) for those leases.

(3) Completely explain all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request.

(4) Include copies of all relevant documents.

(5) Provide your analysis of the issue(s), including citations to all relevant precedents (including adverse precedents).

(6) Suggest your proposed valuation method.

(b) In response to your request, ONRR may:

(1) Request that the Assistant Secretary for Indian Affairs issue a valuation determination.

(2) Decide that ONRR will issue guidance.

(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:

(i) Requests for guidance on hypothetical situations.

(ii) Matters that are the subject of pending litigation or administrative appeals.

(c)(1) A value determination that the Assistant Secretary for Indian Affairs signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.

(2) After the Assistant Secretary issues a value determination, you must make any adjustments to royalty payments that follow from the determination, and, if you owe additional royalties, you must pay the additional royalties due plus late payment interest calculated under § 1218.54 of this chapter.

(3) A value determination that the Assistant Secretary signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.

(d) Guidance that ONRR issues is not binding on ONRR, the Indian lessor, or you with respect to the specific situation addressed in the guidance.

(1) Guidance and ONRR's decision whether or not to issue guidance or request an Assistant Secretary determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under 30 CFR part 1290.

(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under 30 CFR part 1290.

(e) ONRR or the Assistant Secretary may use any of the applicable valuation criteria in this subpart to provide guidance or make a determination.

(f) A change in an applicable statute or regulation on which ONRR or the Assistant Secretary based any determination or guidance takes precedence over the determination or guidance, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the determination or guidance.

(g) ONRR or the Assistant Secretary generally will not retroactively modify or rescind a value determination issued under paragraph (d) of this section, unless:

(1) There was a misstatement or omission of material facts.

(2) The facts subsequently developed are materially different from the facts on which the guidance was based.

(h) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under § 1206.65.

#### § 1206.63 How do I determine royalty quantity and quality?

(a) You must calculate royalties based on the quantity and quality of oil as measured at the point of royalty settlement that BLM approves.

(b) If you determine the value of oil under § 1206.52, § 1206.53, or § 1206.54 based on a quantity and/or quality that is different from the quantity and/or quality at the point of royalty settlement that BLM approves for the lease, you must adjust that value for the differences in quantity and/or quality.

(c) You may not make any deductions from the royalty volume or royalty value for actual or theoretical losses incurred before the royalty settlement point unless BLM determines that any actual loss was unavoidable.

#### § 1206.64 What records must I keep to support my calculations of value under this subpart?

If you determine the value of your oil under this subpart, you must retain all data relevant to the determination of royalty value.

(a) You must show:

(1) How you calculated the value that you reported, including all adjustments for location, quality, and transportation.

(2) How you complied with these rules.

(b) On request, you must make available sales, volume, and transportation data for production that you sold, purchased, or obtained from the field or area. You must make this data available to ONRR, Indian representatives, or other authorized persons.

(c) You can find recordkeeping requirements in §§ 1207.5, 1212.50, and 1212.51 of this chapter.

(d) ONRR, Indian representatives, or other authorized persons may review and audit your data, and ONRR will direct you to use a different value if they determine that the reported value is inconsistent with the requirements of this subpart.

#### § 1206.65 Does ONRR protect information that I provide?

(a) Certain information that you or your affiliate submit(s) to ONRR regarding the valuation of oil, including transportation allowances, may be exempt from disclosure.

(b) To the extent that applicable laws and regulations permit, ONRR will keep confidential any data that you or your affiliate submit(s) that is privileged, confidential, or otherwise exempt from disclosure.

(c) You and others must submit all requests for information under the Freedom of Information Act regulations of the Department of the Interior at 43 CFR part 2.

## PART 1210—FORMS AND REPORTS

■ 3. The authority citation for part 1210 continues to read as follows:

**Authority** 5 U.S.C. 301 *et seq.;* 25 U.S.C. 396, 2107; 30 U.S.C. 189, 190, 359, 1023, 1751(a); 31 U.S.C. 3716, 9701; 43 U.S.C. 1334, 1801 *et seq.;* and 44 U.S.C. 3506(a).

### Subpart B—Royalty Reports—Oil, Gas, and Geothermal Resources

■ 4. Add § 1210.61 to subpart B to read as follows:

#### § 1210.61 What additional reporting requirements must I meet for Indian oil valuation purposes?

(a) If you must report and pay under § 1206.52 of this chapter, you must use Sales Type Code ARMS on Form ONRR–2014.

(b) If you must report and pay under § 1206.53 of this chapter, you must use Sales Type Code NARM on Form ONRR–2014.

(c) If you must report and pay under § 1206.54 of this chapter, you must use Sales Type Code OINX on Form ONRR–2014.

(d) You must report one of the following crude oil types in the product code field of Form ONRR–2014:

(1) Sweet (code 61);

(2) Sour (code 62);

(3) Asphaltic (code 63);

(4) Black Wax (code 64); or

(5) Yellow Wax (code 65).

(e) All of the remaining requirements of this subpart apply.

[FR Doc. 2015–09955 Filed 4–30–15; 8:45 am]

BILLING CODE 4335–30–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2015–0292]**

### Drawbridge Operation Regulation; Annisquam River and Blynman Canal, Gloucester, MA

**AGENCY:** Coast Guard, DHS.

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

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the operation of the Blynman (SR 127) Bridge across the Annisquam River and Blynman Canal, mile 0.0, at Gloucester, Massachusetts. This deviation is necessary to facilitate public safety during a public event, the annual Saint Peter's Fiesta 5K Road Race. This deviation allows the bridge to remain closed for thirty minutes to facilitate public safety.

**DATES:** This deviation is effective from 6:15 p.m. to 6:45 p.m. on June 25, 2015.

**ADDRESSES:** The docket for this deviation, [USCG–2015–0292] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140, on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, contact Ms. Judy K. Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330,

*judy.k.leung-yee@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:** The Blynman (SR 127) Bridge across the Annisquam River and Blynman Canal, mile 0.0, at Gloucester, Massachusetts, has a vertical clearance in the closed position of 8.2 feet at mean high water and 16 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.586.

The owner of the bridge, Massachusetts Department of Transportation, requested a temporary deviation from the normal operating schedule to facilitate a public event, the Annual Saint Peter's Fiesta 5K Road Race.

Under this temporary deviation, the Blynman (SR 127) Bridge may remain in the closed position for thirty minutes between 6:15 p.m. and 6:45 p.m. on Thursday June 25, 2015.

The waterways are transited by commercial and seasonal recreational vessels of various sizes. There is an alternate route for vessel traffic around Cape Ann. Also, vessels that can pass under the closed draws during this closure may do so at all times.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: April 21, 2015.

**C.J. Bisignano,**

*Supervisory Bridge Management Specialist, First Coast Guard District.*

[FR Doc. 2015–10217 Filed 4–30–15; 8:45 am]

**BILLING CODE 9110–04–P**

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 117

**[Docket No. USCG–2015–0132]**

**RIN 1625–AA09**

## Drawbridge Operation Regulation; Manitowoc River, Manitowoc, WI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is removing the existing drawbridge operation regulation for the Wisconsin Central Railroad Bridge, mile 0.91, across Manitowoc River, at Manitowoc, Manitowoc County, Wisconsin. The drawbridge was removed in its entirety in 2012 and the operating regulation is no longer applicable or necessary.

**DATES:** This rule is effective May 1, 2015.

**ADDRESSES:** The docket for this final rule, [USCG–2015–0132] is available at *http://www.regulations.gov*. Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this final rule. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Mr. Lee Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone (216) 902–6085, email *Lee.D.Soule@uscg.mil*. If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

### A. Regulatory History and Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Wisconsin Central Railroad bridge, that once required draw operations in 33 CFR 117.1089, was removed from the waterway in 2012. Therefore, the regulation is no longer applicable and shall be removed from publication. It is unnecessary to publish an NPRM because this regulatory action does not purport to place any restrictions on mariners but rather removes a restriction that has no further use or value. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The bridge has been removed from the waterway for 3 years and this rule merely requires an administrative change to the **Federal Register**, in order to omit a regulatory requirement that is no longer applicable or necessary. The removal has already taken place and the removal of the regulation will not affect mariners currently operating on this waterway. Therefore, a delayed effective date is unnecessary.

### B. Basis and Purpose

The Wisconsin Central Railroad Bridge across the Manitowoc River, mile 0.91, was removed in 2012. It has come to the attention of the Coast Guard that the governing regulation for this drawbridge was never removed subsequent to the removal of the bridge. The elimination of this drawbridge necessitates the removal of the drawbridge operation regulation, 33 CFR 117.1089(b), that pertained to the former drawbridge.

The purpose of this rule is to remove the section of 33 CFR 117.1089 that refers to the Wisconsin Central Railroad Bridge at mile 0.91 from the Code of Federal Regulations since it governs a bridge that has been removed.

### C. Discussion of Rule

The Coast Guard is changing the regulation in 33 CFR 117.1089 by removing restrictions and the regulatory burden related to the draw operations for this bridge that is no longer in existence. This Final Rule seeks to update the Code of Federal Regulations by removing language that governs the operation of the Wisconsin Central Railroad Bridge, which in fact no longer exists. This change does not affect waterway or land traffic. This change does not affect nor does it alter the operating schedules in 33 CFR 117.1089 that governs the remaining active drawbridges on the Manitowoc River.

### D. Regulatory Analyses

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

*1. Regulatory Planning and Review*

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and

does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard does not consider this rule to be ''significant'' under that Order because it is an administrative change and does not affect the way vessels operate on the waterway.

*2. Impact on Small Entities*

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

This rule will have no effect on small entities since this drawbridge has been removed and the regulation governing draw operations for this bridge is no longer applicable. There is no new restriction or regulation being imposed by this rule; therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

*3. Collection of Information*

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

*4. Federalism*

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

*5. Protest Activities*

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

*6. Unfunded Mandates Reform Act*

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

*7. Taking of Private Property*

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

*8. Civil Justice Reform*

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

*9. Protection of Children*

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

*10. Indian Tribal Governments*

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

*11. Energy Effects*

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

*12. Technical Standards*

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

*13. Environment*

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves removing 33 CFR 117.1089(b) from the regulations. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

**List of Subjects in 33 CFR Part 117**

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

## PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

**Authority:** 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

**§ 117.1089 [Amended]**

■ 2. In § 117.1089 remove and reserve paragraph (b).

Dated: April 20, 2015.

**F.M. Midgette,**

*Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.*

[FR Doc. 2015–10238 Filed 4–30–15; 8:45 am]

**BILLING CODE 9110–04–P**

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket No. USCG–2015–0333]**

**RIN 1625–AA00**

## Safety Zone; Floating Construction Platform, Chicago River, Chicago, IL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the South Branch of the Chicago River, Chicago, Illinois. This temporary safety zone is intended to restrict vessels from a designated portion of the South

Branch of the Chicago River due to the transit of a floating construction platform on April 26, 2015, or alternatively on a later date. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the transit of the floating construction platform.

**DATES:** This rule is effective from May 1, 2015 until May 9, 2015.

**ADDRESSES:** Documents mentioned in this preamble are part of docket USCG–2015–0333. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, contact or email MST1 John Ng, U.S. Coast Guard Marine Safety Unit Chicago, at (630) 986–2122 or *John.H.Ng@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:**

## Table of Acronyms

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

## A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because doing so would be impracticable and contrary to public interest. On April 22, 2015, the Coast Guard established a temporary safety zone to accommodate the transit of the floating construction platform, which was scheduled for April 19, 2015 (USCG–2015–0277). However, we recently learned that scheduled transit would be postponed to April 26, 2015. We did not know of this change and the final details for this event until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect participants, spectators and vessels from the hazards associated with this operation, which are discussed further below.

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

## B. Basis and Purpose

The legal basis for this rule is the Coast Guard's authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 160.5; Department of Homeland Security Delegation No. 0170.1.

On April 26, 2015, or alternatively on a later date on or prior to May 9, 2015, a floating construction platform will transit up the South Branch of the Chicago River, Chicago, Illinois from the Canal Street Bridge to the Lake Street Bridge. The Captain of the Port Lake Michigan has determined that the transit of the floating construction platform poses a significant risk to public safety and property. Such hazards include limited maneuverability and restricted visibility associated with the transit of a floating construction platform.

## C. Discussion of the Final Rule

With the aforementioned hazards in mind, the Captain of the Port, Lake Michigan, has determined that this temporary safety zone is necessary to ensure the safety of vessels during the transit of the floating construction platform on the South Branch of the Chicago River. This rule was enforced from 5:00 a.m. to 12:00 p.m. on April 26, 2015. However, enforcement may occur on a later date within this effective period due to an unanticipated delay. In the event of a postponement, advanced notice of the enforcement time will be provided through Broadcast Notice to Mariners. The safety zone will encompass all waters of South Branch of the Chicago River, Chicago, IL, from the Canal Street Bridge to the Lake Street Bridge.

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

## D. Regulatory Analyses

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

### *1. Regulatory Planning and Review*

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

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will only impact a small area of the Chicago River and will be enforced for an estimated period of seven hours on one day between April 25, 2015 and May 9, 2015. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port or a designated on-scene representative.

### *2. Impact on Small Entities*

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this temporary rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in the affected portion of the South Branch of the Chicago River between 5:00 a.m. and 12:00 p.m. on April 26, 2015, or alternatively on a later date.

This safety zone will not have a significant economic impact on a

substantial number of small entities for the reasons cited in the *Regulatory Planning and Review* section. Additionally, before the enforcement of the zone, we would issue local Broadcast Notice to Mariners so vessel owners and operators can plan accordingly.

*3. Assistance for Small Entities*

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

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

*4. Collection of Information*

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

*5. Federalism*

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

*6. Protest Activities*

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

*7. Unfunded Mandates Reform Act*

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

*8. Taking of Private Property*

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

*9. Civil Justice Reform*

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

*10. Protection of Children*

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

*11. Indian Tribal Governments*

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

*12. Energy Effects*

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

*13. Technical Standards*

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

*14. Environment*

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

**List of Subjects in 33 CFR Part 165**

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

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

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0333 to read as follows:

**§ 165.T09–0333 Safety Zone; Floating Construction Platform, Chicago River, Chicago, IL.**

(a) *Location.* All waters of the South Branch of the Chicago River, Chicago, IL, from Canal Street Bridge to Lake Street Bridge.

(b) *Effective and Enforcement Period.* This rule is effective from May 1, 2015 until May 9, 2015. This rule was enforced on April 26, 2015, by actual notice. This rule may be enforced by actual or constructive notice after publication until May 9, 2015.

(c) *Regulations.*

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless

authorized by the Captain of the Port Lake Michigan or a designated on-scene representative.

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

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

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

Dated: April 22, 2015.

**K.M. Moser,**

*Commander, U.S. Coast Guard, Acting Captain of the Port, Lake Michigan.*

[FR Doc. 2015–10215 Filed 4–30–15; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 63

**RIN 2900–AO71**

### Health Care for Homeless Veterans Program

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) amends its medical regulations concerning eligibility for the Health Care for Homeless Veterans (HCHV) program. The HCHV program provides per diem payments to non-VA community-based facilities that provide housing, outreach services, case management services, and rehabilitative services, and may provide care and/or treatment to homeless veterans who are enrolled in or eligible for VA health care. The rule modifies VA's HCHV regulations to conform to changes enacted in the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012. Specifically, the rule removes the requirement that homeless veterans be diagnosed with a serious mental illness or substance use disorder to qualify for the HCHV program. This change makes the program available to all homeless veterans who are enrolled in or eligible for VA health care. The rule also updates the definition of homeless to match in part the one used by the Department of Housing and Urban Development (HUD). The rule further clarifies that the services provided by the HCHV program through non-VA community-based providers must include case management services, including non-clinical case management, as appropriate.

**DATES:** This final rule is effective June 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Robert Hallett, Health Care for Homeless Veterans Manager, c/o Bedford VA Medical Center, Veterans Health Administration, 200 Springs Road, Bldg. 17, Bedford, MA 01730; (781) 687–3187. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** The HCHV program is authorized by section 2031 of title 38, United States Code (U.S.C.), under which VA may provide to eligible veterans outreach; care, treatment, and rehabilitative services (directly or by contract in community-based treatment facilities, including halfway houses); and therapeutic transitional housing assistance, under 38 U.S.C. 2032, in conjunction with work therapy under 38 U.S.C. 1718(a)–(b). Under current regulations, only veterans who are homeless, enrolled in the VA health care system or eligible for VA health care under title 38, Code of Federal Regulations (CFR), § 17.36 or 17.37, and have a serious mental illness and/or substance use disorder are eligible for the program. 38 CFR 63.3(a).

In a document published in the **Federal Register** on May 15, 2014 (79 FR 27826), VA proposed to amend part 63 of 38 CFR to remove the requirement that homeless veterans must suffer from a serious mental illness or substance use disorder to be eligible for HCHV, to modify the definition of the term ''homeless'' to match in part the definition used by HUD, and to require HCHV providers to offer case management services to homeless veterans, as appropriate. We provided a 60-day comment period, which ended on July 14, 2014. We received seven comments, all of which supported the proposed changes to part 63.

One commenter stated that it is shameful that homeless veterans have to be diagnosed with an illness before they can receive the benefits they have earned through military service. Before the enactment of Public Law 112–154, § 302, 126 Stat. 1164, 1184 (Aug. 6, 2012), VA only had authority to provide HCHV services to veterans with serious mental illness, including veterans who are homeless. As amended, the law authorizes VA to make services under the HCHV program available to all homeless veterans VA provides care and services to, regardless of whether they have a serious mental illness. VA fully supports the change in law, and agrees with the commenter that benefits for homeless veterans provided through the HCHV program should not be predicated on a diagnosis of serious mental illness. This regulation will remove that requirement, thereby allowing all eligible homeless veterans to receive services. VA is not making a change based on this comment.

Another commenter asked VA to make the changes in the proposed rule, stating that homeless veterans should be provided resources through the HCHV program regardless of whether or not they have a mental illness. Another commenter stated her wholehearted support for the proposed amendment. Another commenter stated the proposed changes need to be passed. We appreciate the commenters taking the time to review this rulemaking.

Another commenter expressed support for the rule and noted that the proposed change could reduce the social stigma many homeless veterans who do not suffer from a serious mental illness feel about seeking assistance to address their homelessness. Another commenter noted that removing the requirement of a diagnosis for mental illness would also help homeless veterans with serious mental illness access the program, as they may not have been willing to acknowledge their disability before. We agree and believe that these changes will help more homeless veterans, both those with and without a serious mental illness, access the health care services they need through the HCHV program.

One commenter expressed support for the proposed changes, but identified two concerns. First, the commenter urged VA to request increased funding and resources to accommodate the number of new enrollees that would be eligible as a result of the proposed rule. Second, the commenter stated their concern that the proposed rule could have the unintended effect of disadvantaging homeless veterans with a serious mental illness if HCHV providers find that veterans without a mental illness are easier to place or receive the bulk of the services available. While the first comment is somewhat outside the scope of this rule, VA will take into account the changes made as a result of this rule when

determining the resources it will allocate for the HCHV program. However, VA notes that the rule should not result in any increased expense to the Department, as it only modifies the pool of eligible persons, rather than the number of persons served. As explained in the proposed rule, the principal driver of costs is bed availability, which would not change as a result of this rule. Similarly, and also in response to the second comment, VA has found that the supply of HCHV services generally exceeds demand, so we do not believe there will be a shift in emphasis or a reduction in services from homeless veterans with a serious mental illness. Further, the HCHV provider would be prohibited from engaging in discrimination by virtue of entering into a contract with VA as a recipient of Federal financial assistance. Pursuant to 38 CFR 63.10(a)–(b), HCHV providers must enter into a contract with VA in order to be granted financial assistance. VA is authorized by section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 706, 794) and VA's implementing regulations in subpart D, part 18, 38 CFR to prohibit discrimination against persons on the basis of handicap by any party that receives Federal financial assistance. Under these authorities, any HCHV provider is prohibited from discriminating against beneficiaries on the basis of a disability, including a serious mental illness.

Based on the rationale set forth in the proposed rule and in this document, VA is adopting the proposed rule as a final rule with no changes.

**Effect of Rulemaking**

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

**Paperwork Reduction Act**

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

**Regulatory Flexibility Act**

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule removes the requirement that veterans have a serious mental illness to participate in the HCHV program and clarifies that the HCHV program includes case management services. This rule only impacts those entities that choose to participate in the HCHV program. As of June 2014, approximately 300 non-profit entities participate in the HCHV program. We do not expect this rule to result in any additional costs or economic impacts on these entities, as the rule modestly expands the population of veterans eligible to receive care and requires case management services consistent with current practice. Small entity applicants will not be affected to a greater extent than large entity applicants. Small entities must elect to participate, and this clarification simply reinforces the services these entities are already providing. The expanded population of eligible veterans will not result in any additional costs because the principal driver of cost is bed availability, which will not change as a result of this rule. To the extent this rule will have any impact on small entities, it will not have an impact on a substantial number of small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

**Executive Orders 12866 and 13563**

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm,* by following the link for VA Regulations Published from FY 2004 through FYTD.

**Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

**Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

**Signing Authority**

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the

Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on April 24, 2015, for publication.

**List of Subjects in 38 CFR Part 63**

Administrative practice and procedure, Day care, Disability benefits, Government contracts, Health care, Homeless, Housing, Individuals with disabilities, Low and moderate income housing, Public assistance programs, Public housing, Relocation assistance, Reporting and recordkeeping requirements, Veterans.

Dated: April 27, 2015.

**William F. Russo,**

*Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.*

For the reasons set forth in the preamble, VA amends 38 CFR part 63 as follows:

## PART 63—HEALTH CARE FOR HOMELESS VETERANS (HCHV) PROGRAM

■ 1. The authority citation for part 63 continues to read as follows:

**Authority:** 38 U.S.C. 501, 2031, and as noted in specific sections.

■ 2. Revise § 63.1 to read as follows:

### § 63.1 Purpose and scope.

This part implements the Health Care for Homeless Veterans (HCHV) program. This program provides per diem payments to non-VA community-based facilities that provide housing, outreach services, case management services, and rehabilitative services, and may provide care and/or treatment to all eligible homeless veterans.

(Authority: 38 U.S.C. 501, 2031(a)(2))

■ 3. Amend § 63.2 by:

■ a. Adding the definition ''Case management'' in alphabetical order.

■ b. Revising the definitions of ''Homeless'' and ''Non-VA community-based provider''.

■ c. Removing the definitions of ''Serious mental illness'' and ''Substance use disorder''.

■ d. Revising the authority citation at the end of the section.

The addition and revisions read as follows:

### § 63.2 Definitions.

* * * * *

*Case management* means arranging, coordinating, or providing direct clinical services and support; referring and providing linkage to VA and non-VA resources, providing crisis management services and monitoring; and intervening and advocating on behalf of veterans to support transportation, credit, legal, and other needs.

* * * * *

*Homeless* has the meaning given that term in paragraphs (1) through (3) of the definition of homeless in 24 CFR 576.2.

*Non-VA community-based provider* means a facility in a community that provides temporary, short-term housing (generally up to 6 months) for the homeless, as well as community outreach, case management, and rehabilitative services, and, as needed, basic mental health services.

* * * * *

(Authority: 38 U.S.C. 501, 2002, 2031)

■ 4. Amend § 63.3 by revising paragraph (a) to read as follows:

### § 63.3 Eligible Veterans.

(a) Eligibility. In order to serve as the basis for a per diem payment through the HCHV program, a veteran served by the non-VA community-based provider must be:

(1) Enrolled in the VA health care system, or eligible for VA health care under 38 CFR 17.36 or 17.37; and

(2) Homeless.

* * * * *

### § 63.10 [Amended]

■ 5. Amend § 63.10 by revising paragraph (a) to read as follows:

(a) *Who can apply.* VA may award per diem contracts to non-VA community-based providers who provide temporary residential assistance homeless persons, including but not limited to persons with serious mental illness, and who can provide the specific services and meet the standards identified in § 63.15 and elsewhere in this part.

* * * * *

■ 6. Amend § 63.15 by revising paragraph (b) to read as follows:

### § 63.15 Duties of, and standards applicable to, non-VA community-based providers.

* * * * *

(b) *Treatment plans, therapeutic/rehabilitative services, and case management.* Individualized treatment plans are to be developed through a joint effort of the veteran, non-VA community-based provider staff, and VA clinical staff. Therapeutic and rehabilitative services, as well as case management and outreach services, must be provided by the non-VA community-based provider as described in the treatment plan. In some cases, VA may complement the non-VA community-based provider's program with added treatment or other services, such as participation in VA outpatient programs or counseling. In addition to case management services, for example, to coordinate or address relevant issues related to a veteran's homelessness and health as identified in the individual treatment plan, services provided by the non-VA community-based provider should generally include, as appropriate:

(1) Structured group activities such as group therapy, social skills training, self-help group meetings, or peer counseling.

(2) Professional counseling, including counseling on self-care skills, adaptive coping skills, and, as appropriate, vocational rehabilitation counseling, in collaboration with VA programs and community resources.

* * * * *

[FR Doc. 2015–10150 Filed 4–30–15; 8:45 am]

BILLING CODE 8320–01–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[EPA–R09–OAR–2015–0087; FRL–9926–77–Region 9]**

## Approval of Air Quality Implementation Plans; California; South Coast Air Quality Management District; Stationary Source Permits

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to approve Rule 1325, Federal $PM_{2.5}$ New Source Review Program, into the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). This action was proposed in the **Federal Register** on February 17, 2015. Rule 1325 governs the issuance of permits for major stationary sources and major modifications located in areas designated as nonattainment for the $PM_{2.5}$ NAAQS to meet Clean Air Act Part D requirements for emissions of $PM_{2.5}$ and $PM_{2.5}$ precursors. EPA is taking this action under the Clean Air Act obligation to take action on State submittals for inclusion in state implementation plans. The intended effect is to update the SIP with nonattainment new source review (NNSR) rules for major stationary sources and major modifications emitting $PM_{2.5}$ and certain $PM_{2.5}$ precursors.

**DATES:** This rule is effective on June 1, 2015.

**ADDRESSES:** EPA has established docket number [EPA–R09–OAR–2015–0087] for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Laura Yannayon, EPA Region IX, by phone: (415) 972–3534 or by email at *yannayon.laura@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to EPA.

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I. Proposed Action
II. Public Comment
III. EPA Action and Response to Health Advocates Comment
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## I. Proposed Action

On February 17, 2015 (80 FR 8250), EPA proposed approval of South Coast Air Quality Management District (SCAQMD) Rule 1325, Federal $PM_{2.5}$ New Source Review Program, for inclusion in the California SIP. Rule 1325 was adopted by SCAQMD on December 5, 2014, and submitted by the California Air Resources Board on December 29, 2014.

## II. Public Comment

EPA's proposed action provided a 30-day public comment period. During this time we received two comments. Only one of the comments, submitted by Earthjustice on behalf of Health Advocates [1], objected to our proposed approval of SCAQMD Rule 1325.

## III. EPA Action and Response to Health Advocates Comment

The letter submitted on behalf of Health Advocates objected to EPA's proposed approval of Rule 1325 on three grounds. Below we provide a summary of our response to each of Health Advocates' comments. Please see the Response to Comments document in the docket for this final action for our complete response.

1. Approval of exclusion of ammonia as a precursor.

CAA subpart 4 includes section 189(e), which requires NNSR controls for major stationary sources of $PM_{10}$ precursors, and hence $PM_{2.5}$ precursors, ''except where the Administrator determines that *such sources* do not contribute significantly to $PM_{10}$ levels which exceed the standard in the area.'' CAA section 189(e) (Emphasis added). EPA has identified ammonia as a precursor to the formation of $PM_{2.5}$. See generally 80 FR 15340, 15352 (Mar, 23, 2015) (Proposed $PM_{2.5}$ Implementation Rule). EPA proposed to approve Rule 1325 even though it does not contain NNSR requirements for ammonia emissions because SCAQMD provided information that demonstrates major stationary sources of ammonia emissions do not contribute significantly to $PM_{2.5}$ levels exceeding the $PM_{2.5}$ National Ambient Air Quality Standard (NAAQS) in the South Coast Air Basin nonattainment area. 80 FR at 8251.

Health Advocates disagreed with our proposal on three grounds, asserting that (1) EPA's determination that a contribution of 1.7 tons per day (tpd) of ammonia emissions to the ammonia inventory is small is ''unjustified''; (2) EPA has not demonstrated that ammonia emissions do not contribute significantly to $PM_{2.5}$ NAAQS violations in the South Coast Air Basin; and (3) it was arbitrary and capricious for EPA to consider the trends and actual air quality of $PM_{2.5}$ in the area. Earthjustice Letter at p.3.

EPA disagrees with these comments. EPA applied a weight of the evidence approach taking into account several factors to determine if SCAQMD appropriately determined that major stationary sources of ammonia emissions do not contribute significantly to $PM_{2.5}$ nonattainment in the area.

One factor we considered is that there are only four existing major stationary sources of ammonia and these four sources' emissions are only a small percentage (1.7%) of the total ammonia inventory for the South Coast $PM_{2.5}$ nonattainment area. Health Advocates did not submit any information or provide an explanation to show that 1.7% is not a small percentage. Health Advocates did not indicate what percentage would be justified as being small. For reasons explained fully in our Response to Comments, EPA continues to consider the 1.7% contribution of ammonia emissions from the four existing stationary sources to be relatively small compared to the rest of the ammonia inventory.

A second factor we considered is whether major stationary sources of ammonia contribute significantly to levels exceeding the $PM_{2.5}$ NAAQS in the area, and whether potential new major stationary sources would be expected to contribute significantly to levels exceeding the $PM_{2.5}$ NAAQS in the area. The SCAQMD provided information showing that a regional increase of 10 tpd of ammonia (more than five times the amount currently emitted by all major stationary sources) would result in a 0.22 microgram per cubic meter ($\mu g/m^3$) increase in annual $PM_{2.5}$ concentrations. This estimated increase in annual $PM_{2.5}$ concentration would be 1.5% of the 15 $\mu g/m^3$ 1997 $PM_{2.5}$ annual standard. SCAQMD submitted additional information showing that decreasing ammonia emissions by 2.9 tpd near the Mira Loma monitor would result in a reduction of 0.16 $\mu g/m^3$ at that monitor.[2] This estimated increase in 24-hr $PM_{2.5}$ concentration would be 0.46% of the 35 $\mu g/m^3$ 1997 $PM_{2.5}$ 24-hr standard. Based on these data, one can reasonably conclude that the current ambient contribution (in $\mu g/m^3$) of the four existing major stationary sources (with emissions of 1.7 tpd) and the ambient contributions from a new major source, to $PM_{2.5}$ levels that exceed the standard are likely to be less than the estimated changes in $PM_{2.5}$ concentrations indicated in the analyses cited above (which evaluated emission changes of 10 tpd and 2.9 tpd, respectively). Thus, EPA determined that existing and new major stationary sources of ammonia would make a relatively minor contribution to levels exceeding the 1997 or 2006 $PM_{2.5}$ NAAQS in the area.

A third factor we considered was the progress the SCAQMD has made and the overall severity of the $PM_{2.5}$ nonattainment problem in the South Coast Air Basin. Health Advocates contends it was arbitrary and capricious to consider the past progress and current air quality and asserts that our evaluation of the air quality is flawed. We disagree with both points. EPA's General Preamble in 1992 noted that determinations under CAA section 189(e) are case-by-case and depend on a variety of information that is specific

[1] Health Advocates consists of Communities for a Better Environment, Physicians for Social Responsibility-Los Angeles, and Sierra Club My Generation Campaign.

[2] Draft Supplement to the 24-Hour $PM_{2.5}$ State Implementation Plan for the South Coast Air Basin dated January 2015 at E–1.

to the area. See 57 FR 13498, 13538–42 (April 16, 1992). EPA's proposed $PM_{2.5}$ Implementation Rule recently reiterated that application of section 189(e) should be case-specific and focused on location, including a weight of the evidence approach considering, among other factors, the severity of the nonattainment problem in the area. 80 FR at 15359. Therefore, it is appropriate to consider this factor.

Health Advocates also asserted that EPA's discussion of the air quality in the South Coast Air Basin was misleading, contending that there were violations of both the 1997 and 2006 $PM_{2.5}$ NAAQS. Earthjustice Letter at p. 3–4. EPA acknowledges one monitor (Mira Loma) has recorded $PM_{2.5}$ emissions exceeding the level of the 2006 24-hour $PM_{2.5}$ NAAQS based on 2011–2013 air quality data. However, Health Advocates failed to provide any information to support its claims that there are any current violations of the 1997 $PM_{2.5}$ NAAQS. The information Health Advocates cited to support its allegations of additional violations of the 2006 $PM_{2.5}$ NAAQS at the Mira Loma monitor is from a combination of both federal and non-federal reference method monitors. In in addition the data is preliminary, uncertified and has not been quality assured.

Based on the weight of the evidence, EPA concludes that it was appropriate for SCAQMD to exclude ammonia as a precursor pursuant to CAA section 189(e).

2. Regulation of VOCs by SCAQMD NNSR Rule 1303 rather than Rule 1325.

Health Advocates also disagreed with EPA's proposal to approve Rule 1325 without requiring VOC emissions to be included in the Rule's requirements. Id at p. 4. Health Advocates contends our proposal is inconsistent with CAA section 189(e).

EPA did not propose to determine that VOCs do not contribute significantly to $PM_{2.5}$ levels that exceed the $PM_{2.5}$ standards and is making no such finding in this final rule. Instead, consistent with the proposed rule, EPA is determining that the NNSR control requirements applicable under the SCAQMD SIP for major stationary sources of $PM_{2.5}$ also apply to major stationary sources of VOCs (which are $PM_{2.5}$ precursors), because major VOC sources are currently subject to stringent NNSR control requirements under Rule 1303. The requirements in Rule 1303 [3] are more stringent than those that would apply under Rule 1325 and fully satisfy the control requirements of CAA section 189(e) with respect to VOCs.[4] Moreover, it is long-standing EPA policy to allow NNSR regulation of PM precursors via their regulation through other NNSR programs. 57 FR at 13542 (''The VOC reductions may also be realized from new or modified major stationary sources due to the implementation of NSR programs in ozone nonattainment or attainment areas'').

We continue to find that the NNSR regulation of VOC emissions pursuant to Rule 1303 rather than Rule 1325 satisfies the requirements of section 189(e).

3. Consideration of attainment of the $PM_{2.5}$ NAAQS.

Finally, Health Advocates contends that EPA cannot approve Rule 1325 because the South Coast Air Basin has not demonstrated the area is in attainment with the 1997 and 2006 $PM_{2.5}$ NAAQS. Earthjustice Letter at p. 5.

There is no requirement for the area to have attained the $PM_{2.5}$ NAAQS as a predicate for EPA to approve a new NNSR rule for $PM_{2.5}$. Approval of a new NNSR rule to control emissions of $PM_{2.5}$, including $NO_X$, $SO_2$ and VOCs [5] emissions as precursors, in no way interferes with the SCAQMD's progress towards attaining the 1997 and 2006 $PM_{2.5}$ NAAQS.

No comments were submitted to change our assessment of Rule 1325 as described in our proposed action. Pursuant to section 110(k) of the CAA and for the reasons provided in our proposed action, associated TSD and detailed Response to Comments document included in the docket, EPA is finalizing approval of SCAQMD Rule 1325.

## IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SCAQMD rules described in the amendments to 40 CFR 52.220 set forth below. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

## V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or

[3] SCAQMD Regulation XIII establishes the NNSR program requirements for VOC emissions from stationary sources. Rule 1303 references other SCAQMD rules in Regulation XIII. Our citation to Rule 1303 also includes any other provisions in Regulation XIII as applicable.

[4] Section 189(e) of the CAA states that ''[t]he control requirements applicable under plans in effect under this part for major stationary sources of $PM_{10}$ shall also apply to major stationary sources of $PM_{10}$ precursors,'' except where the Administrator makes specific findings.

[5] As noted above, major stationary sources of VOC emissions are regulated pursuant to a different, more stringent NNSR rule (Rule 1303) rather than Rule 1325.

in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 30, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: April 14, 2015.

**Jared Blumenfeld,**

*Regional Administrator, Region IX.*

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

## PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

### Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(458) to read as follows:

**§ 52.220 Identification of plan.**

* * * * *

(c) * * *

(458) New and amended regulations for the following APCDs were submitted on December 29, 2014 by the Governor's designee.

(i) Incorporation by Reference.

(A) South Coast Air Quality Management District.

(*1*) Rule 1325, Rule 1325, ''Federal $PM_{2.5}$ New Source Review Program'' adopted on December 5, 2014.

[FR Doc. 2015–10239 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2014–0248; FRL–9926–24]**

## Azoxystrobin; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of azoxystrobin in or on coffee, green bean; pear, Asian; and tea, dried. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) to cover residues of azoxystrobin in coffee, Asian pear, and tea imported into the United States; there are currently no U.S. registrations for pesticides containing azoxystrobin that are used on coffee, Asian pear, or tea.

**DATES:** This regulation is effective May 1, 2015. Objections and requests for hearings must be received on or before June 30, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0248, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0248 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or

before June 30, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0248, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL–9910–29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8228) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide azoxystrobin, in or on coffee, bean, green at 0.03 parts per million (ppm); pear, Asian at 0.07 ppm and tea at 10 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has increased the tolerance on tea from what the petitioner requested. The reason for this change is explained in Unit IV.D.

## III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for azoxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with azoxystrobin follows.

### *A. Toxicological Profile*

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

Azoxystrobin has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant and is not a skin sensitizer. Repeated oral dosing of azoxystrobin to rats resulted in decreased body weights, decreased food intake and utilization, increased diarrhea, and other clinical toxicity observations (increased urinary incontinence, hunched postures, and distended abdomens). In addition, liver effects characterized by increased liver weights, increase in alkaline phosphatase and gamma glutamyltransferase, decrease in albumin, and gross and histological lesions in the liver and bile ducts, were seen in rats. In dogs, effects on liver/biliary function were found after oral administration.

In the acute neurotoxicity study in rats, increased incidence of diarrhea was observed at all dose levels tested. Decreases in body weight and food utilization were noted in the rat subchronic neurotoxicity study. There were no indications of treatment-related neurotoxicity in either the acute or subchronic neurotoxicity studies.

In the rat developmental toxicity study, diarrhea, urinary incontinence, and salivation were observed in maternal animals; in the rabbit developmental toxicity study, maternal animals exhibited decreased body weight gain. No adverse treatment-related developmental effects were seen in either study. In the rat reproduction study, offspring and parental effects (decreased body weights and increased adjusted liver weights) were observed at the same dose.

There was no evidence of carcinogenicity in rats and mice. As a result, EPA has classified azoxystrobin as ''not likely to be carcinogenic to humans.'' Azoxystrobin induced a weak mutagenic response in the mouse lymphoma assay, but the activity expressed *in vitro* is not expected to be expressed in whole animals.

Specific information on the studies received and the nature of the adverse effects caused by azoxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''Human Health Aggregate Risk Assessment for Permanent Tolerances on Imported Asian Pear, Imported Tea, and Imported Coffee; Establishment of Permanent Tolerances on Ti Palm and for Crop Group Conversions for Stone Fruits Group 12–12 and Tree Nut Group 14–12 Crop Groups'' on page 5 in docket ID number EPA–HQ–OPP–2014–0248.

### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction

with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AZOXYSTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Acute dietary (All Populations) | LOAEL = 200 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 3x | Acute RfD = 0.67mg/kg/day.<br>aPAD = 0.67 mg/kg/day | Acute Neurotoxicity—Rat.<br>LOAEL = 200 mg/kg/day based on diarrhea at two-hours post dose at all dose levels tested. |
| Chronic dietary (All populations) | NOAEL = 18 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Chronic RfD = 0.18 mg/kg/day.<br>cPAD = 0.18 mg/kg/day | Combined Chronic Toxicity/Carcinogenicity Feeding Study—Rat.<br>LOAEL = 82.4/117 mg/kg/day (M/F) based on reduced body weights in both sexes and bile duct lesions in males. |
| Incidental oral short-term (1 to 30 days) & intermediate-term (1 to 6 months) | NOAEL = 35 mg/kg/day.<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | 2-Generation Reproduction Study—Rat.<br>LOAEL = 165 mg/kg/day based on decreased pup weights in both males and females (↓8–21%). |
| Dermal (All durations) | No hazard was identified for this exposure scenario. | | 21-Day Repeated Dose Dermal Study—Rat. No dermal or systemic toxicity was seen at the limit dose (1,000 mg/kg/day). |
| Inhalation [1] short-term (1 to 30 days) & intermediate-term (1 to 6 months) | NOAEL = 35 mg/kg/day [2].<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | 2-Generation Reproduction Study—Rat.<br>LOAEL = 165 mg/kg/day based on decreased pup weights in both males and females (↓8–21%). |
| Cancer (Oral, dermal, inhalation). | Azoxystrobin is classified as "Not Likely" to be carcinogenic to humans. | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure.

NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies).

[1] To protect for the body weight decreases seen in the pups, a 69 kg body weight was used for estimating short- and intermediate-term inhalation doses because the pup body weight decrease also influenced by the maternal health.

[2] Toxicity via the inhalation route is assumed to be equivalent to the oral route.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to azoxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing azoxystrobin tolerances in 40 CFR 180.507. EPA assessed dietary exposures from azoxystrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for azoxystrobin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the acute dietary assessment incorporated tolerance-level residues for all commodities except for citrus fruits (which used the highest residues from residue trials); 100 percent crop treated (PCT); and Dietary Exposure Evaluation Model (DEEM) (ver. 3.16) default processing factors, except for where tolerances were established for processed commodities or when processing studies showed no concentration. Field trial data were translated from the representative commodities to the non-representative commodities according to HED SOP 2000.1''Guidance for Translation of Field Trial Data from Representative Commodities in the Crop Group Regulation to other Commodities in Each Crop Group/Subgroup.''

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis incorporated tolerance-level residues for all commodities, average PCT estimates when available and DEEM (ver. 3.16) default processing factors, except for where tolerances

were established for processed commodities or when processing studies showed no concentration.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that azoxystrobin should be classified as ''not likely'' to be carcinogenic to humans. Therefore a cancer risk assessment is unnecessary.

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

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

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

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

The Agency estimated the PCT for the chronic dietary exposure assessment for existing uses as follows: Almonds, 20%; apricots, 10%; artichokes, 20%; asparagus, <2.5%; barley, <2.5%; green beans, 15%; blueberries, 15%; broccoli, 10%; cabbage, 10%; cane berries, 5%; cantaloupes, 20%; carrots, 10%; cauliflower, <2.5%; celery, 10%; corn, <2.5%; cotton, <2.5%; cotton (seed treatment), 25%; cucumbers, 20%; dry beans/peas, <2.5%; eggplant, 30%; garlic, 70%; grapefruit, 20%; grapes, 5%; hazelnuts, 5%; lemons, <2.5%; lettuce, <2.5%; nectarines, <2.5%; onions, 5%; oranges, 5%; peaches, 5%; peanuts, 20%; peanuts (seed treatment), 30%; green peas, <2.5%; pecans, 5%; peppers, 20%; pistachios, 5%; plums/prunes, <2.5%; potatoes, 40%; potatoes (seed treatment), <1%; pumpkins, 20%; rice, 40%; soybeans, 5%; soybeans (seed treatment), <1%; spinach, 10%; squash, 20%; strawberries, 25%; sugar beets, 10%; sugar beets (seed treatment), <2.5%; sweet corn, 15%; tangelos, 25%; tangerines, 10%; tobacco, 15%; tomatoes, 25%; walnuts, >2.5%; watermelons, 15%; wheat, 5%; wheat seed (seed treatment), <1%.

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

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which azoxystrobin may be applied in a particular area.

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

Based on the Screening Concentration in Ground Water (SCI–GROW) model and Pesticide Root Zone Model Ground Water (PRZM GW), for surface water, the estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 70.2 parts per billion (ppb) and for chronic exposures are estimated to be 48.5 ppb. For ground water, the estimated drinking water concentration for both acute and chronic exposure scenarios is 3.1 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 70.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 48.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Azoxystrobin is currently registered for the following uses that could result in residential exposures: Outdoor residential (lawns, ornamentals, flower gardens, vegetables, fruit and nut trees, berries and vines) and recreational (golf courses, parks and athletic fields) sites. Additionally, it is registered for use on indoor carpets/other surfaces by non-commercial applicators, and in treated paints (preservative incorporation).

The proposed uses do not impact the aggregate risk assessment; however, the scenarios that do impact the aggregate assessment have been re-evaluated in this assessment to reflect the revised incidental oral and inhalation PODs. Using those new PODs, EPA assessed residential exposure using the 2012 updated residential standard operating procedures (SOPs) that are now used in all human health assessments.

For the adult aggregate assessment, the Agency used inhalation exposure from adult handlers applying treated paint via airless sprayers; for the aggregate assessment for children, the Agency used post-application inhalation exposure from space-trays and hand-to-mouth exposures from indoor applications to treated carpets for children 1 to <2 years old.

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

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

*D. Safety Factor for Infants and Children*

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

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for azoxystrobin includes prenatal developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in young rats. In these studies, there is no evidence that azoxystrobin results in increased quantitative sensitivity to developing fetuses. Also in the reproduction study, the offspring and the parental effects occurred at the same dose level.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all exposure scenarios except acute exposure. For assessing acute dietary risk, EPA is retaining an FQPA factor of 3X to account for the use of a LOAEL from the acute neurotoxicity study to derive an acute reference dose. The Agency believes that a 3X FQPA SF (as opposed to a 10X) will be adequate to extrapolate a NOAEL in assessing acute risk based on the following considerations:

- The LOAEL is based on a transient effect (diarrhea in rats) expected to be relatively insignificant in nature. This effect is also seen in other chemicals of the same class.
- The diarrhea was only seen in studies using gavage dosing in the rat, but not in studies using repeat dosing through dietary administration in rats or mice, and not through gavage dosing in rabbits.
- The very high dose level needed to reach the acute oral lethal dose $(LD)_{50}$ (≤ 5000 mg/kg), and the overall low toxicity of azoxystrobin.

The decision to reduce the FQPA safety factor to 1X for the assessment of the remaining exposure scenarios is based on the following findings:

i. The toxicity database for azoxystrobin is complete.

ii. There is no indication that azoxystrobin is a neurotoxic chemical. Although clinical signs were observed in the acute and subchronic neurotoxicity studies which included transient diarrhea, decreased body weight, body weight gain, and food utilization, no other effects were seen in those studies that would be considered indicative of neurotoxicity. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that azoxystrobin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. In the reproduction study, the offspring and the parental effects occurred at the same dose level.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary (food) exposure assessments utilized conservative upper-bound inputs including assuming 100% CT and tolerance-level residues for all commodities except citrus fruits where the highest field trial residue was used as a refinement. The chronic dietary exposure assessment was partially refined, and used tolerance-level residues for all commodities and PCT information for selected crops. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to azoxystrobin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by azoxystrobin.

*E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 40% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to azoxystrobin from food and water will utilize 15% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of azoxystrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Azoxystrobin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to azoxystrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,400 for adults and 280 for children 1–2 years old. Because EPA's

level of concern for azoxystrobin is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no intermediate-term adverse effect was identified, azoxystrobin is not expected to pose an intermediate-term risk. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate.

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

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

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

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

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

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established a MRL for azoxystrobin in or on coffee, bean at 0.03 ppm. The US tolerance for coffee is harmonized with the Codex MRL. The Codex has not established a MRL for Asian pear or tea.

### *C. Response to Comments*

One comment was received in response to the notice of filing of Syngenta Crop Protection's petition. The commenter objected to the increase of chemical residues generally and expressed additional concerns about the carcinogenic effects of chemicals in general on humans. The Agency understands the commenter's concerns regarding toxic chemicals and their potential effects on humans. Pursuant to its authority under the FFDCA, and as discussed further in this preamble, EPA conducted a comprehensive assessment of azoxystrobin, which included an assessment on the carcinogenic potential of azoxystrobin. Based on its assessment of the available data, the Agency has concluded that azoxystrobin is not likely to be a carcinogen and that there is a reasonable certainty that no harm will result from aggregate exposure to residues of azoxystrobin.

### *D. Revisions to Petitioned-For Tolerances*

The tolerance on tea has been revised from what was proposed in the initial petition. EPA is increasing the proposed tolerance for tea from 10 ppm to 20.0 ppm. The proposed tolerance of 10 ppm for tea is insufficient, as the trials were conducted at 50% of the label maximum rate. Correction by proportionality to the maximum label rate provides a tolerance recommendation of 20.0 ppm. Also, because magnitude of residue data used to determine the appropriate tolerance level were provided for dried tea only, EPA is only establishing a tolerance for dried tea at this time.

In addition, EPA is altering the commodity name for ''coffee, green bean'' from the petitioned-for name (''coffee, bean, green'') to be consistent with the general food and feed commodity vocabulary EPA uses for tolerances and exemptions.

## V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin, in or on coffee, green bean at 0.03 ppm; pear, Asian at 0.07 ppm; and tea, dried at 20.0 ppm.

## VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as

described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

### VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 23, 2015.

**Susan Lewis,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

■ 2. In § 180.507:

■ a. Add alphabetically the entries for ''Coffee, green bean''; [1] ''Pear, Asian'',[1] ''Tea, dried'' [1] to the table in paragraph (a)(1).

■ b. Revise footnote [1] at the end of the table in paragraph (a)(1).

The additions and revision read as follows:

**§ 180.507 Azoxystrobin; tolerances for residues.**

(a) * * *

(1) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Coffee, green bean [1] | 0.03 |
| * * * * * | |
| Pear, Asian [1] | 0.07 |
| * * * * * | |
| Tea, dried [1] | 20.0 |
| * * * * * | |

[1] There are no United States registrations for use of azoxystrobin on coffee, green bean; ginseng; pear, Asian and tea, dried.

* * * * *

[FR Doc. 2015–10149 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

## 44 CFR Part 64

**[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–8381]**

## Suspension of Community Eligibility

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

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

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

**FOR FURTHER INFORMATION CONTACT:** If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Bret Gates, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4133.

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

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

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are

met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

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

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

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

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

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

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

**List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

## PART 64—[AMENDED]

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

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

### § 64.6 [Amended]

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

| State and location | Community No. | Effective date authorization/cancellation of sale of flood insurance in community | Current effective map date | Date certain Federal assistance no longer available in SFHAs |
|---|---|---|---|---|
| **Region II** | | | | |
| New York: | | | | |
| Cairo, Town of, Greene County | 360286 | October 3, 1975, Emerg; September 6, 1989, Reg; June 2, 2015, Susp. | June 2, 2015 | June 2, 2015 |
| Hunter, Town of, Greene County | 360292 | November 12, 1976, Emerg; February 2, 1983, Reg; June 2, 2015, Susp. | *-do- | Do. |
| Hunter, Village of, Greene County | 360293 | October 1, 1976, Emerg; December 1, 1982, Reg; June 2, 2015, Susp. | ....do | Do. |
| Jewett, Town of, Greene County | 361114 | May 13, 1980, Emerg; April 4, 1983, Reg; June 2, 2015, Susp. | ....do | Do. |
| Lexington, Town of, Greene County | 360294 | September 12, 1975, Emerg; August 1, 1983, Reg; June 2, 2015, Susp. | ....do | Do. |
| Tannersville, Village of, Greene County | 360297 | July 15, 1975, Emerg; April 18, 1983, Reg; June 2, 2015, Susp. | ....do | Do. |
| **Region III** | | | | |
| Virginia: | | | | |
| Prince George County, Unincorporated Areas. | 510204 | May 17, 1974, Emerg; May 1, 1980, Reg; June 2, 2015, Susp. | ....do | Do. |
| **Region IV** | | | | |
| North Carolina: | | | | |
| Edgecombe County, Unincorporated Areas. | 370087 | August 6, 1975, Emerg; August 3, 1981, Reg; June 2, 2015, Susp. | ....do | Do. |
| Halifax County, Unincorporated Areas | 370327 | November 22, 1976, Emerg; May 5, 1981, Reg; June 2, 2015, Susp. | ....do | Do. |
| Leggett, Town of, Edgecombe County | 370317 | March 4, 1997, Emerg; December 20, 1999, Reg; June 2, 2015, Susp. | ....do | Do. |
| Macclesfield, Town of, Edgecombe County. | 370090 | March 25, 1980, Emerg; March 25, 1980, Reg; June 2, 2015, Susp. | ....do | Do. |
| Pinetops, Town of, Edgecombe County | 370091 | November 7, 1975, Emerg; March 28, 1980, Reg; June 2, 2015, Susp. | ....do | Do. |
| Princeville, Town of, Edgecombe County. | 370318 | August 9, 1976, Emerg; April 15, 1980, Reg; June 2, 2015, Susp. | ....do | Do. |
| Speed, Town of, Edgecombe County | 370093 | September 4, 1979, Emerg; July 2, 1987, Reg; June 2, 2015, Susp. | ....do | Do. |
| Tarboro, Town of, Edgecombe County | 370094 | February 15, 1974, Emerg; January 5, 1978, Reg; June 2, 2015, Susp. | ....do | Do. |
| **Region V** | | | | |
| Indiana: | | | | |
| Andrews, Town of, Huntington County | 180097 | July 28, 1982, Emerg; September 30, 1982, Reg; June 2, 2015, Susp. | ....do | Do. |
| Huntington, City of, Huntington County | 180094 | August 8, 1975, Emerg; July 18, 1983, Reg; June 2, 2015, Susp. | ....do | Do. |

| State and location | Community No. | Effective date authorization/cancellation of sale of flood insurance in community | Current effective map date | Date certain Federal assistance no longer available in SFHAs |
|---|---|---|---|---|
| Huntington County, Unincorporated Areas. | 180438 | August 21, 1978, Emerg; July 18, 1983, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Markle, Town of, Huntington and Wells Counties. | 180457 | N/A, Emerg; November 7, 1991, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Roanoke, Town of, Huntington County | 180096 | July 28, 1982, Emerg; December 1, 1982, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Warren, Town of, Huntington County .... | 180095 | February 19, 1975, Emerg; September 30, 1982, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| **Region VI** | | | | |
| Oklahoma: | | | | |
| Kiowa, Town of, Pittsburg County ..... | 400168 | N/A, Emerg; May 11, 2012, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Pittsburg County, Unincorporated Areas | 400494 | November 26, 2002, Emerg; November 1, 2007, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| **Region VIII** | | | | |
| Utah: | | | | |
| Ogden, City of, Weber County ..... | 490189 | December 27, 1974, Emerg; January 19, 1983, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Riverdale, City of, Weber County ..... | 490190 | October 4, 1974, Emerg; February 3, 1982, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Roy, City of, Weber County ..... | 490223 | January 16, 1976, Emerg; October 24, 1978, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| South Ogden, City of, Weber County ... | 490191 | August 2, 1974, Emerg; March 1, 1982, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Uintah, City of, Weber County ..... | 490192 | April 30, 1974, Emerg; May 19, 1981, Reg; June 2, 2015, Susp. | .....do ..... | Do. |
| Weber County, Unincorporated Areas .. | 490187 | March 25, 1975, Emerg; July 19, 1982, Reg; June 2, 2015, Susp. | .....do ..... | Do. |

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

Dated: April 27, 2015.

**Roy E. Wright,**

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

[FR Doc. 2015–10229 Filed 4–30–15; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 622

**[Docket No. 150226189–5389–02]**

**RIN 0648–BE91**

## Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Management Measures

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

**ACTION:** Final rule.

**SUMMARY:** NMFS implements management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) prepared by the Gulf of Mexico (Gulf) Fishery Management Council (Council). The final rule increases commercial and recreational quotas for red snapper in the Gulf of Mexico reef fish fishery for the 2015, 2016, and 2017 fishing years. Quotas for subsequent fishing years would remain at 2017 levels unless changed by future rulemaking. This rule also announces the closure dates for the red snapper recreational sector components (private angling and for-hire components) in the Gulf. The private angling component will close at 12:01 a.m., local time, June 11, 2015, and the for-hire component will close at 12:01 a.m., local time, on July 15, 2015. This rule is intended to help achieve optimum yield for the Gulf red snapper resource without increasing the risk of red snapper experiencing overfishing.

**DATES:** This rule is effective June 1, 2015.

**ADDRESSES:** Electronic copies of the 2015 Gulf red snapper framework action, which includes an environmental assessment, Regulatory Flexibility Act (RFA) analysis and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish.*

**FOR FURTHER INFORMATION CONTACT:** Cynthia Meyer, telephone 727–824–5305; email: *Cynthia.Meyer@noaa.gov.*

**SUPPLEMENTARY INFORMATION:** NMFS and the Council manage the Gulf reef fish fishery, including red snapper, under the FMP. The Council prepared the FMP and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On April 1, 2015, NMFS published a proposed rule for the framework action and requested public comment (80 FR 17380). The proposed rule and the framework action set forth the rationale for the actions contained in this final rule. A summary of the actions implemented by this final rule is provided below.

### Management Measures Contained in This Final Rule

This final rule sets the commercial and recreational quotas (equal to the

commercial and recreational annual catch limit (ACLs)) and the recreational annual catch targets (ACTs) for the 2015, 2016, and 2017 fishing years for red snapper based on the acceptable biological catch levels chosen by the Council, as recommended by its Scientific and Statistical Committee, and on the current commercial and recreational allocations (51-percent commercial and 49-percent recreational). Quotas for subsequent fishing years will remain at 2017 levels unless changed by future rulemaking. All values contained in this final rule are given in round weight. For 2015, the commercial quota is set at 7.293 million lb (3.308 million kg) and the recreational quota is set at 7.007 million lb (3.178 million kg); for 2016, the commercial quota is set at 7.120 million lb (3.230 million kg) and the recreational quota is set at 6.840 million lb (3.103 million kg); and for 2017 and subsequent fishing years, the commercial quota is set at 7.007 million lb (3.178 million kg) and the recreational quota is set at 6.733 million lb (3.054 million kg).

Based on the revised recreational quotas contained in this final rule, the revised recreational ACTs for the 2015, 2016, and 2017 fishing years are as follows: 5.606 million lb (2.543 million kg) for 2015; 5.472 million lb (2.482 million kg) for 2016; and 5.384 million lb (2.442 million kg) for 2017. Recreational ACTs for subsequent fishing years will remain at 2017 levels unless changed by future rulemaking.

Implementation of Amendment 40 to the FMP established two components within the recreational sector for Gulf red snapper (a Federal charter vessel/headboat (for-hire) component and a private angling component), allocated the red snapper recreational quota and ACT between the components, and established separate seasonal closures for the two components. These component quotas and ACTs are effective through 2017. In addition, the final rule for Amendment 40 established ACLs for the commercial and recreational sectors, which are equal to the commercial and recreational quotas, respectively. The Secretary of Commerce approved Amendment 40 on April 10, 2015, and a final rule published on April 22, 2015 (80 FR 22422), effective May 22, 2015.

Based on the component allocations set in Amendment 40 and the increased recreational quotas (equal to the recreational ACLs) contained in this final rule, the resulting recreational component quotas and ACTs are as follows. The for-hire component quota and private angling component quota, respectively, are: 2.964 million lb (1.344 million kg) and 4.043 million lb (1.834 million kg) for 2015; 2.893 million lb (1.312 million kg) and 3.947 million lb (1.790 million kg) for 2016; 2.848 million lb (1.292 million kg) and 3.885 million lb (1.762 million kg) for 2017. The for-hire component ACT and private angling component ACT, respectively, are: 2.371 million lb (1.075 million kg) and 3.234 million lb (1.467 million kg) for 2015; 2.315 million lb (1.050 million kg) and 3.158 million lb (1.432 million kg) for 2016; and 2.278 million lb (1.033 million kg) and 3.108 million lb (1.410 million kg) for 2017.

## Red Snapper Recreational Fishing Season

In accordance with 50 CFR 622.34(b) and 50 CFR 622.41(q)(2)(i), the red snapper recreational fishing season opens each year on June 1 and closes when the applicable component ACT is projected to be reached. To project the 2015 recreational fishing season lengths, NMFS used finalized 2014 landings data, catch rates for each state, state season lengths, as well as other information. The method used to project these season lengths can be found in SERO–LAPP–2015–04: 2015 Gulf of Mexico Red Snapper Recreational Season Length Estimates on the SERO Web site. After analysis of the information referenced above, NMFS determined that the season for the private angling component is 10 days and the season for the for-hire component is 44 days. As required by 50 CFR 622.34(b) and 50 CFR 622.41(q)(2)(i), NMFS announces the closure dates for the recreational sector components (private angling and for-hire components) in the Gulf through this final rule. NMFS opens both components on June 1 and closes the private angling component at 12:01 a.m., local time, June 11, 2015, and the for-hire component at 12:01 a.m., local time, on July 15, 2015.

## Additional Changes to Codified Text

This final rule makes two administrative changes to the Gulf Individual Fishing Quota (IFQ) program regulations. In §§ 622.21 and 622.22, the Web site for the Gulf IFQ program changes from ''*ifq.sero.fisheries.noaa.gov*'' to ''*https://portal.southeast.fisheries.noaa.gov/cs/main.html*'' to align with the renaming of NMFS Web sites for all of the regions in the U.S. In § 622.21(b)(6)(ii), NMFS revises the minimum share transfer percentage for the Gulf red snapper IFQ program from ''0.0001 percent'' to ''0.000001 percent'' to align with the Gulf grouper/tilefish program minimum share transfer percentage and allows for smaller percentages of red snapper IFQ shares to be transferred. When the red snapper IFQ program was implemented in 2007, NMFS determined, based on the share cap and red snapper commercial quota, that 0.0001 percent was the appropriate minimum share transfer percentage. Because the red snapper commercial quota has been increasing, NMFS has now determined that the minimum share transfer percentage should be 0.000001 percent. This gives shareholders greater flexibility by allowing transfers of smaller increments of shares. In addition, modifying the minimum share transfer percentage for red snapper helps avoid confusion among shareholders who trade both red snapper and grouper/tilefish shares because both programs have the same minimum share transfer percentage.

## Comments and Responses

During the comment period, NMFS received 20 comments, including 17 from private anglers, 1 from a recreational fishing organization, and 2 from charter fishermen. Comments pertinent to the rule unanimously supported increasing the red snapper quota and did not raise any additional issues within the scope of this rulemaking. NMFS agrees with the commenters that the quota increases are appropriate, and are in accordance with the red snapper rebuilding plan.

Many of these same commenters provided additional observations and suggestions for alternative strategies to manage the recreational red snapper harvest that were beyond the scope of the rule. The Council has considered many of the public suggestions in the past and may consider alternative management options for the recreational harvest of red snapper in the future. NMFS agrees that alternative recreational management strategies may prove to be viable options for the management of red snapper in the future; however, these comments and suggestions are beyond the scope of this rulemaking and will not be further addressed in this rule.

## Classification

The Regional Administrator, Southeast Region, NMFS determined that this final rule and the framework action are necessary for the conversation and management of Gulf red snapper and are consistent with the FMP, the Magnuson-Stevens Act and other applicable law.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. No comments were received regarding the certification and NMFS has not received any new information that would affect its determination. As a result, neither an initial nor final regulatory flexibility analysis was required and therefore, neither was prepared.

**List of Subjects in 50 CFR Part 622**

Commercial, Fisheries, Fishing, Gulf of Mexico, Quotas, Recreational, Red Snapper.

Dated: April 27, 2015.

**Samuel D. Rauch III,**

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

For the reasons set out in the preamble, 50 CFR part 622 is 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.*

■ 2. In § 622.21, the third sentence in paragraph (b)(1), the second sentence in paragraph (b)(2), the last sentence in paragraph (b)(3)(i), the first sentence in paragraph (b)(3)(iii), the second sentence in paragraph (b)(3)(iv), the only sentence in paragraph (b)(5)(i)(B), the third sentence in paragraph (b)(5)(v), the second and third sentences in paragraph (b)(6)(ii), the second sentence in paragraph (b)(6)(iv), and the first sentence in paragraph (b)(10) are revised to read as follows:

### § 622.21 Individual fishing quota (IFQ) program for Gulf red snapper.

* * * * *

(b) * * *

(1) * * * An owner of a vessel with a commercial vessel permit for Gulf reef fish, who has established an IFQ account for Gulf red snapper as specified in paragraph (a)(3)(i) of this section, online via the NMFS IFQ Web site *https://portal.southeast.fisheries.noaa.gov/cs/main.html,* may establish a vessel account through that IFQ account for that permitted vessel. * * *

(2) * * * A dealer with a Gulf and South Atlantic dealer permit can download a Gulf IFQ dealer endorsement from the NMFS IFQ Web site. * * *

(3) * * *

(i) * * * All IFQ landings and their actual ex-vessel prices must be reported via the IFQ Web site.

* * * * *

(iii) The dealer must complete a landing transaction report for each landing of Gulf red snapper via the IFQ Web site on the day of offload, except if the fish are being trailered for transport to a dealer as specified in paragraph (b)(5)(iv) of this section (in which case the landing transaction report may be completed prior to the day of offload), and within 96 hours from the time of landing reported on the most recent landing notification, in accordance with the reporting form(s) and instructions provided on the Web site. * * *

(iv) * * * This form is available via the IFQ Web site. * * *

* * * * *

(5) * * *

(i) * * *

(B) * * * Authorized methods for contacting NMFS and submitting the report include calling IFQ Customer Service at 1–866–425–7627, completing and submitting to NMFS a landing notification provided through the VMS unit, or providing the required information to NMFS through the web-based form available on the IFQ Web site.

* * * * *

(v) * * * Proposed landing locations may be submitted online via the IFQ Web site, or by calling IFQ Customer Service at 1–866–425–7627, at any time; however, new landing locations will be approved only at the end of each calendar-year quarter. * * *

* * * * *

(6) * * *

(ii) * * * An IFQ shareholder must initiate a share transfer request by logging onto the IFQ Web site. Following the instructions provided on the IFQ Web site, the shareholder must enter pertinent information regarding the transfer request including, but not limited to, amount of shares to be transferred, which must be a minimum of 0.000001 percent; name of the eligible transferee; and the value of the transferred shares. * * *

* * * * *

(iv) * * * An IFQ account holder must initiate an allocation transfer by logging onto the IFQ Web site, entering the required information, including but not limited to, name of an eligible transferee and amount of IFQ allocation to be transferred and price, and submitting the transfer electronically. * * *

* * * * *

(10) * * * On or about January 1 each year, IFQ shareholders will be notified, via the IFQ Web site, of their IFQ share and allocation for the upcoming fishing year. * * *

* * * * *

■ 3. In § 622.22, the third sentence in paragraph (b)(1), the second sentence in paragraph (b)(2), the last sentence in paragraph (b)(3)(i), the first sentence in paragraph (b)(3)(iii), the second sentence in paragraph (b)(3)(iv), the only sentence in paragraph (b)(5)(i)(B), the third sentence in paragraph (b)(5)(v), the second sentence in paragraph (b)(6)(ii), the second sentence in paragraph (b)(6)(iv), and the first sentence in paragraph (b)(10) are revised to read as follows:

### § 622.22 Individual fishing quota (IFQ) program for Gulf groupers and tilefishes.

* * * * *

(b) * * *

(1) * * * An owner of a vessel with a commercial vessel permit for Gulf reef fish, who has established an IFQ account for the applicable species, as specified in paragraph (a)(3)(i) of this section, online via the NMFS IFQ Web site *https://portal.southeast.fisheries.noaa.gov/cs/main.html,* may establish a vessel account through that IFQ account for that permitted vessel. * * *

(2) * * * A dealer with a Gulf and South Atlantic dealer permit can download a Gulf IFQ dealer endorsement from the NMFS IFQ Web site. * * *

(3) * * *

(i) * * * All IFQ landings and their actual ex-vessel prices must be reported via the IFQ Web site.

* * * * *

(iii) The dealer must complete a landing transaction report for each landing of Gulf groupers or tilefishes via the IFQ Web site on the day of offload, except if the fish are being trailered for transport to a dealer as specified in paragraph (b)(5)(iv) of this section (in which case the landing transaction report may be completed prior to the day of offload), and within 96 hours from the time of landing reported on the most recent landing notification, in accordance with the reporting form(s) and instructions provided on the Web site. * * *

(iv) * * * This form is available via the IFQ Web site. * * *

* * * * *

(5) * * *

(i) * * *

(B) * * * Authorized methods for contacting NMFS and submitting the report include calling IFQ Customer Service at 1–866–425–7627, completing and submitting to NMFS a landing notification provided through the VMS unit, or providing the required information to NMFS through the web-based form available on the IFQ Web site.

* * * * *

(v) * * * Proposed landing locations may be submitted online via the IFQ Web site, or by calling IFQ Customer Service at 1–866–425–7627, at any time; however, new landing locations will be approved only at the end of each calendar-year quarter. * * *

* * * * *

(6) * * *

(ii) * * * An IFQ shareholder must initiate a share transfer request by logging onto the IFQ Web site. * * *

* * * * *

(iv) * * * An IFQ account holder must initiate an allocation transfer by logging onto the IFQ Web site, entering the required information, including but not limited to, the name of an eligible transferee and amount of IFQ allocation to be transferred and price, and submitting the transfer electronically. * * *

* * * * *

(10) * * * On or about January 1 each year, IFQ shareholders will be notified, via the IFQ Web site, of their IFQ shares and allocations, for each of the five share categories, for the upcoming fishing year. * * *

* * * * *

■ 4. In § 622.39, paragraphs (a)(1)(i) and (a)(2)(i) are revised to read as follows:

**§ 622.39 Quotas.**

* * * * *

(a) * * *

(1) * * *

(i) *Commercial quota for red snapper.* (A) For fishing year 2015—7.293 million lb (3.308 million kg), round weight.

(B) For fishing year 2016—7.120 million lb (3.230 million kg), round weight.

(C) For fishing year 2017 and subsequent fishing years—7.007 million lb (3.178 million kg), round weight.

* * * * *

(2) * * *

(i) *Recreational quota for red snapper.* (A) *Total recreational quota (Federal charter vessel/headboat and private angling component quotas combined).*

(*1*) For fishing year 2015—7.007 million lb (3.178 million kg), round weight.

(*2*) For fishing year 2016—6.840 million lb (3.103 million kg), round weight.

(*3*) For fishing year 2017 and subsequent fishing years—6.733 million lb (3.054 million kg), round weight.

(B) *Federal charter vessel/headboat component quota.* The Federal charter vessel/headboat component quota applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component quota is effective for only the 2015, 2016, and 2017 fishing years. For the 2018 and subsequent fishing years, the applicable total recreational quota specified in § 622.39(a)(2)(i)(A) will apply to the recreational sector.

(*1*) For fishing year 2015—2.964 million lb (1.344 million kg), round weight.

(*2*) For fishing year 2016—2.893 million lb (1.312 million kg), round weight.

(*3*) For fishing year 2017—2.848 million lb (1.292 million kg), round weight.

(C) *Private angling component quota.* The private angling component quota applies to vessels that fish under the bag limit and have not been issued a Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component quota is effective for only the 2015, 2016, and 2017 fishing years. For the 2018 and subsequent fishing years, the applicable total recreational quota specified in § 622.39(a)(2)(i)(A) will apply to the recreational sector.

(*1*) For fishing year 2015—4.043 million lb (1.834 million kg), round weight.

(*2*) For fishing year 2016—3.947 million lb (1.790 million kg), round weight.

(*3*) For fishing year 2017—3.885 million lb (1.762 million kg), round weight.

* * * * *

■ 5. In § 622.41, paragraph (q) is revised to read as follows:

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

* * * * *

(q) *Red snapper*—(1) *Commercial sector.* The IFQ program for red snapper in the Gulf of Mexico serves as the accountability measure for commercial red snapper. The commercial ACL for red snapper is equal to the applicable commercial quota specified in § 622.39(a)(1)(i).

(2) *Recreational sector.* (i) The AA will determine the length of the red snapper recreational fishing season based on when recreational landings are projected to reach the applicable recreational ACT specified in paragraph (q)(2)(iii) of this section, and announce the closure date in the **Federal Register**. This will serve as an in-season accountability measure. On and after the effective date of the recreational closure notification, the bag and possession limit for red snapper is zero. The recreational ACL is equal to the applicable total recreational quota specified in § 622.39(a)(2)(i).

(ii) In addition to the measures specified in paragraph (q)(2)(i) of this section, if red snapper recreational landings, as estimated by the SRD, exceed the applicable recreational ACL (quota) specified in § 622.39(a)(2)(i), and red 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 reduce the recreational ACL (quota) by the amount of the quota overage in the prior fishing year, and reduce the applicable recreational ACT specified in paragraph (q)(2)(iii) of this section (based on the buffer between the ACT and the quota specified in the FMP), unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

(iii) *Recreational ACT for red snapper.* (A) *Total recreational ACT (Federal charter vessel/headboat and private angling component ACTs combined).*

(*1*) For fishing year 2015—5.606 million lb (2.543 million kg), round weight.

(*2*) For fishing year 2016—5.472 million lb (2.482 million kg), round weight.

(*3*) For fishing year 2017 and subsequent fishing years—5.384 million lb (2.442 million kg), round weight.

(B) *Federal charter vessel/headboat component ACT.* The Federal charter vessel/headboat component ACT applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component ACT is effective for only the 2015, 2016, and 2017 fishing years. For the 2018 and subsequent fishing years, the applicable total recreational quota specified in § 622.39(a)(2)(i)(A) will apply to the recreational sector.

(*1*) For fishing year 2015—2.371 million lb (1.075 million kg), round weight.

(*2*) For fishing year 2016—2.315 million lb (1.050 million kg), round weight.

(*3*) For fishing year 2017—2.278 million lb (1.033 million kg), round weight.

(C) *Private angling component ACT.* The private angling component ACT applies to vessels that fish under the bag limit and have not been issued a Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component ACT is effective for only the 2015, 2016, and 2017 fishing years. For the 2018 and subsequent fishing years, the applicable total recreational quota specified in § 622.39(a)(2)(i)(A) will apply to the recreational sector.

(*1*) For fishing year 2015—3.234 million lb (1.467 million kg), round weight.

(*2*) For fishing year 2016—3.158 million lb (1.432 million kg), round weight.

(*3*) For fishing year 2017—3.108 million lb (1.410 million kg), round weight.

[FR Doc. 2015–10088 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 635

**[Docket No. 140429387–4971–02]**

**RIN 0648–XD911**

## Atlantic Highly Migratory Species; Commercial Blacktip Sharks, Aggregated Large Coastal Sharks, and Hammerhead Sharks in the Gulf of Mexico Region

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is closing the commercial fisheries for blacktip sharks, aggregated large coastal sharks (LCS), and hammerhead sharks in the Gulf of Mexico region. This action is necessary because the commercial landings of blacktip sharks in the Gulf of Mexico region for the 2015 fishing season are projected to exceed 80 percent of the available commercial quota as of May 1, 2015, commercial landings of aggregated LCS in the Gulf of Mexico region have exceeded 80 percent of the available commercial quota, and the aggregated LCS and hammerhead shark fisheries are quota-linked under the current regulations.

**DATES:** The commercial fisheries for blacktip sharks, aggregated LCS, and hammerhead sharks are closed effective 11:30 p.m. local time May 3, 2015, until the end of the 2015 fishing season on December 31, 2015, or until and if NMFS announces via a notice in the **Federal Register** that additional quota is available and the season is reopened.

**FOR FURTHER INFORMATION CONTACT:** Alexis Jackson or Karyl Brewster-Geisz 301–427–8503; fax 301–713–1917.

**SUPPLEMENTARY INFORMATION:** The Atlantic shark fisheries are managed under the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), its amendments, and implementing regulations (50 CFR part 635) issued under authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

Under § 635.5(b)(1), dealers must electronically submit reports on sharks that are first received from a vessel on a weekly basis through a NMFS-approved electronic reporting system. Reports must be received by no later than midnight, local time, of the first Tuesday following the end of the reporting week unless the dealer is otherwise notified by NMFS. Under § 635.28(b)(2), the quotas of certain species/fisheries and/or management groups are linked. If quotas are linked, when the specified quota threshold for one management group or species/fishery is reached and is closed, the linked management group or fishery closes at the same time. The quotas for aggregated LCS and the hammerhead shark management groups in the Gulf of Mexico region are linked (§ 635.28(b)(3)(ii)). The blacktip shark quota is not linked to the aggregated LCS or hammerhead shark quotas. Regulations at § 635.28(b)(1) and § 635.28(b)(4) authorize closure of the blacktip shark management group when landings have reached or are expected to reach 80 percent of the quota or before those situations occur.

Under § 635.28(b)(1) and § 635.28(b)(2), when NMFS calculates that the landings for any species and/or management group of either a non-linked or a linked group have reached or are projected to reach a threshold of 80 percent of the available quota, NMFS will file for publication with the Office of the Federal Register a notice of closure for all of the species and/or management groups of either a non-linked or linked group that will be effective no fewer than 5 days from date of filing. From the effective date and time of the closure until and if NMFS announces, via a notice in the **Federal Register**, that additional quota is available and the season is reopened, the fisheries for all linked species and/or management groups and specified non-linked species and/or management groups are closed, even across fishing years.

On December 2, 2014 (79 FR 71331), NMFS announced that the commercial Gulf of Mexico blacktip shark quota was 328.6 mt dw (724,302 lb dw), the Gulf of Mexico aggregated LCS quota for 2015 was 156.5 metric tons (mt) dressed weight (dw) (344,980 lb dw), and the Gulf of Mexico hammerhead shark quota was 25.3 mt dw (55,722 lb dw). Dealer reports recently received through April 24, 2015, indicate that that 261.1 mt dw or 79 percent of the available Gulf of Mexico blacktip shark quota has been landed, 128.6 mt dw or 82 percent of the available Gulf of Mexico aggregated LCS quota has been landed, and that 12.4 mt dw or 49 percent of the available Gulf of Mexico hammerhead shark quota has been landed. Based on these dealer reports, NMFS estimates that the 80-percent limit specified for a closure notice in the regulations for blacktip sharks will be exceeded as of May 1, 2015, and has been exceeded for aggregated LCS. Accordingly, NMFS is closing the commercial blacktip, aggregated LCS, and hammerhead management groups in the Gulf of Mexico region as of 11:30 p.m. local time May 3, 2015. All other shark species or management groups that are currently open will remain open, including the commercial Gulf of Mexico non-blacknose small coastal sharks (SCS), blacknose sharks, blue sharks, and pelagic sharks other than porbeagle or blue.

At § 635.27(b)(1), the boundary between the Gulf of Mexico region and the Atlantic region is defined as a line beginning on the East Coast of Florida at the mainland at 25°20.4′ N. lat, proceeding due east. Any water and land to the south and west of that boundary is considered for the purposes of monitoring and setting quotas, to be within the Gulf of Mexico region.

During the closure, retention of blacktip sharks, aggregated LCS, and/or hammerhead sharks in the Gulf of Mexico region is prohibited for persons fishing aboard vessels issued a commercial shark limited access permit under § 635.4. However, persons aboard a commercially permitted vessel that is also properly permitted to operate as a charter vessel or headboat for HMS and is engaged in a for-hire trip could fish under the recreational retention limits for sharks and ''no sale'' provisions (§ 635.22(a) and (c)). Similarly, persons

aboard a commercially permitted vessel that possesses a valid shark research permit under § 635.32 and has a NMFS-approved observer onboard may continue to harvest and sell blacktip sharks, aggregated LCS, and/or hammerhead sharks in the Gulf of Mexico region pursuant to the terms and conditions of the shark research permit.

During this closure, a shark dealer issued a permit pursuant to § 635.4 may not purchase or receive blacktip sharks, aggregated LCS, and/or hammerhead sharks in the Gulf of Mexico region from a vessel issued an Atlantic Shark Limited Access Permit (LAP), except that a permitted shark dealer or processor may possess blacktip sharks, aggregated LCS, and/or hammerhead sharks in the Gulf of Mexico region that were harvested, off-loaded, and sold, traded, or bartered prior to the effective date of the closure and were held in storage consistent with § 635.28(b)(5). Additionally, a permitted shark dealer or processor may possess blacktip sharks, aggregated LCS, and/or hammerhead sharks in the Gulf of Mexico region that were harvested by a vessel issued a valid shark research fishery permit per § 635.32 with a NMFS-approved observer onboard during the trip the sharks were taken on as long as the LCS research fishery quota remains open. Similarly, a shark dealer issued a permit pursuant to § 635.4 may, in accordance with relevant state regulations, purchase or receive blacktip sharks, aggregated LCS, and/or hammerhead sharks in the Gulf of Mexico region if the sharks were harvested, off-loaded, and sold, traded, or bartered from a vessel that fishes only in state waters and that has not been issued an Atlantic Shark LAP, HMS Angling permit, or HMS Charter/Headboat permit pursuant to § 635.4.

## Classification

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA (AA), finds that providing prior notice and public comment for this action is impracticable and contrary to the public interest because the fishery is currently underway and any delay in this action would result in overharvest of the quota and be inconsistent with management requirements and objectives. Similarly, affording prior notice and opportunity for public comment on this action is contrary to the public interest because if the quota is exceeded, the stock may be negatively affected and fishermen ultimately could experience reductions in the available quota and a lack of fishing opportunities in future seasons. For these reasons, the AA also finds good cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(d)(3). This action is required under § 635.28(b)(2) and is exempt from review under Executive Order 12866.

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

Dated: April 27, 2015.

**Emily H. Menashes,**

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

[FR Doc. 2015–10165 Filed 4–28–15; 4:15 pm]

BILLING CODE 3510–22–P

# Proposed Rules

Federal Register
Vol. 80, No. 84
Friday, May 1, 2015

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

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 7 CFR Part 319

**[Docket No. APHIS–2015–0005]**

**RIN 0579–AE09**

## Importation of Citrus From Peru; Expansion of Citrus-Growing Area

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the fruits and vegetable regulations to allow citrus fruit from the entire country of Peru into the continental United States. Currently, the regulations allow the importation of citrus fruit to the United States from five approved citrus-producing zones in Peru, subject to a systems approach. However, based on the findings of a pest list and commodity import evaluation document, we have determined that this systems approach also mitigates the plant pest risk associated with citrus fruit produced in all other areas of Peru. This action would allow the importation of citrus fruit from the entire country of Peru while continuing to provide protection against the introduction of plant pests into the continental United States.

**DATES:** We will consider all comments that we receive on or before June 30, 2015.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docket Detail;D=APHIS-2015-0005.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0005, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0005* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Mr. Tony Román, Senior Regulatory Policy Specialist, PPQ, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 851–2242.

**SUPPLEMENTARY INFORMATION:**

### Background

The regulations in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–71, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests within the United States.

Under § 319.56–41, grapefruit (*Citrus paradisi*), limes (*C. aurantiifolia*), mandarins or tangerines (*C. reticulata*), sweet oranges (*C. sinensis*), and tangelos (*C. tangelo*) may be imported into the United States from approved growing areas in Peru under a systems approach designed to mitigate the risk presented by four species of fruit flies (*Anastrepha fracterculus, A. obliqua* Macquart, *A. serpentina,* and *Ceratitis capitata*) and a Tortricid (*Ecdytolopha aurantiana*). The systems approach requires the following:

- The fruit must be accompanied by a permit issued in accordance with § 319.56–3(b);
- The fruit may be imported in commercial consignments only;
- The fruit must be grown in an approved growing area (Zone I, Piura; Zone II, Lambayeque; Zone III, Lima; Zone IV, Ica; Zone V, Junin);
- The production site where the fruit is grown must be registered for export with the national plant protection organization (NPPO) of Peru, and the producer must have signed an agreement with the NPPO of Peru whereby the producer agrees to participate in and follow the fruit fly management program established by the NPPO of Peru;
- The NPPO of Peru's fruit fly management program must be approved by the Animal and Plant Health Inspection Service (APHIS), must require participating citrus producers to allow APHIS inspectors access to production areas in order to monitor compliance with the fruit fly management program, and must follow certain trapping, control, and recordkeeping requirements;
- The fruit, except limes, must be cold treated for fruit flies in accordance with 7 CFR part 305;
- Each consignment of fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Peru stating that the fruit has been inspected and found free of *E. aurantiana;* and
- Citrus fruits imported from Peru are subject to inspection and sampling by an inspector at the port of first arrival into the United States in accordance with § 319.56–3(d), and if a single living fruit fly in any stage of development or *E. aurantiana* is found, the consignment will be held until an investigation is completed and appropriate remedial actions have been implemented.

The NPPO of Peru has requested that APHIS amend the regulations to allow citrus fruit from the entire country of Peru to be imported into the continental United States.

As part of our evaluation of Peru's request, we prepared a pest list, titled ''Pest List for the Importation of Fresh Commercial Citrus Fruit: Grapefruit (*Citrus x paradisi*); Lime (*C. aurantiifolia*); Mandarin Orange, Tangerine, or Hybrids (*C. reticulata*); Sweet Orange (*C. sinensis*); and Tangelo (*C.* x *tangelo*) from Peru into the Continental United States'' (November 2012). The pest list examines the plant pest risks associated with the importation of citrus from the entire country of Peru into the continental United States. The pest list identified the same four fruit flies and one Tortricid identified in the 2003 pest risk assessment for the importation of citrus from the five zones in Peru as potentially following the pathway of citrus fruit from the entire country of Peru to the United States.

Based on the pest list, we prepared a commodity import evaluation document (CIED), titled, ''Expansion of Areas Allowed to Export Fresh Commercial Citrus Fruit Including Grapefruit (*Citrus x paradisi*); Lime (*C. aurantiifolia*);

Mandarin Orange, Tangerine, or Hybrids (*C. reticulata*); Sweet Orange (*C. sinensis*); and Tangelo (*C.* x *tangelo*) from Peru into the Continental United States'' (November 2012), to assess the risks associated with the importation of citrus from the entire country of Peru and recommend mitigation measures to prevent the introduction and dissemination of plant pests and diseases of quarantine concern. The CIED recommends applying the systems approach in § 319.56–41 to citrus fruit from the entire country of Peru.

Based on the conclusions of the pest list and CIED, we are proposing to amend the regulations to allow the importation of citrus from the entire country of Peru into the continental United States under the systems approach in § 319.56–41. Specifically, we are proposing to remove paragraph (c), which contains the list of approved growing areas that are allowed to export citrus to the United States, and redesignate the subsequent paragraphs.

Currently, the regulations allow the importation of citrus from Peru into the United States, including Hawaii and the U.S. Territories. Between 2006 and 2012, Peru shipped small consignments to one U.S. Territory, Puerto Rico, but has never exported citrus fruit to Hawaii or the other U.S. territories. As a result, in preparing this rule, we asked the NPPO of Peru whether they intended to ship to markets in Hawaii and the U.S. Territories in the future. Peru indicated that they do not intend to do so, and that their request for market access could be limited to the continental United States. As a result, the pest list and CIED prepared for this proposed rule only evaluated the risk associated with the importation of citrus from Peru into the continental United States, which excludes Hawaii and the U.S. Territories. Therefore, we are proposing to amend the introductory text of the section to limit the importation of citrus from Peru to the continental United States.

**Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

Currently, the regulations allow the importation of fresh grapefruit, lime, mandarin, orange, tangerine or hybrids, sweet orange, and tangelo from five approved citrus-producing zones in Peru to the United States. The proposed rule would allow the importation of these fruits from the entire country of Peru into the continental United States under the same conditions that are currently in place. The proposed rule is expected to increase the area in Peru approved to produce citrus for export to the United States to about 1,500 hectares over 3 years. Additional volumes of citrus expected to be shipped to the United States are 5,000 metric tons (MT) in the first year that the rule is in effect, 6,500 MT in the second year, and 8,000 MT in the third year. These quantities are equivalent to less than 1 percent of annual U.S. citrus production or U.S. citrus imports.

The primary entities that may be affected by the rule are citrus producers, citrus importers, and support industries such as packinghouses. Based on data from the 2012 Census of Agriculture and Small Business Administration small-entity standards, the majority of these operations are small.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

**Executive Order 12988**

This proposed rule would allow fresh citrus to be imported from Peru into the continental United States. If this proposed rule is adopted, State and local laws and regulations regarding fresh citrus imported under this rule would be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

**Paperwork Reduction Act**

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2015–0005. Please send a copy of your comments to: (1) APHIS, using one of the methods described under **ADDRESSES** at the beginning of this document, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

APHIS is proposing to amend the fruits and vegetables regulations to allow the importation of fresh citrus into the continental United States from Peru. As a condition of entry, the fruit would have to be produced in accordance with a systems approach that would include requirements for fruit fly trapping and monitoring, production sites, recordkeeping, and inspections designed to exclude quarantine pests. The fruit would also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the NPPO of Peru stating that the fruit has been inspected and found free of *E. aurantiana.* At the port of first arrival, an inspector will sample and cut citrus fruits from each consignment to detect pest infestation.

Allowing the importation of fresh citrus into the continental United States from Peru will require information collection activities, including permit applications to import plants or plant products, registered production sites and agreements, fruit fly trapping and control, trapping records, and phytosanitary certificates.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are

to respond (such as 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).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 2.6 hours per response.

*Respondents:* NPPO of Peru, producers/growers, and importers.

*Estimated annual number of respondents:* 67.

*Estimated annual number of responses per respondent:* 14.

*Estimated annual number of responses:* 912.

*Estimated total annual burden on respondents:* 2,334 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**E-Government Act Compliance**

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**List of Subjects in 7 CFR Part 319**

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

## PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

**Authority:** 7 U.S.C. 450, 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

**§ 319.56–41 [Amended]**

■ 2. Section 319.56–41 is amended as follows:

■ a. In the introductory text, by adding the word ''continental'' between the words ''the'' and ''United States''.

■ b. By removing paragraph (c).

■ c. By redesignating paragraphs (d) through (h) as paragraphs (c) through (g), respectively.

Done in Washington, DC, this 27th day of April 2015.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015–10199 Filed 4–30–15; 8:45 am]

**BILLING CODE 3410–34–P**

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 9 CFR Part 3

**[Docket No. APHIS–2014–0098]**

### Petition To Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of petition.

**SUMMARY:** We are notifying the public that the Animal and Plant Health Inspection Service has received a petition requesting that we amend the Animal Welfare Act regulations to specify ethologically appropriate standards that researchers must adhere to in order to promote the psychological well-being of nonhuman primates used in research. We are making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition that we should take into account as we consider this petition.

**DATES:** We will consider all comments that we receive on or before June 30, 2015.

**ADDRESSES:** You may submit comments by either of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docket Detail;D=APHIS-2014-0098.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0098, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0098* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Dr. Carol Clarke, Research Program Manager, USDA, APHIS, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 851–3751.

**SUPPLEMENTARY INFORMATION:** The Animal Welfare Act (AWA, 7 U.S.C. 2131 *et seq.*), among other things, authorizes the Secretary of Agriculture (Secretary) to promulgate standards and other requirements governing research facilities. The Secretary has delegated the responsibility for enforcing the AWA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for Animal Care.

Regulations and standards promulgated under the AWA are contained in Title 9 of the Code of Federal Regulations, parts 1, 2, and 3 (referred to collectively below as the AWA regulations). Part 3 of the AWA regulations contains specific standards regarding the humane handling, care, treatment, and transportation of species of animals covered under the AWA.

Within part 3 of the AWA regulations, subpart D (§§ 3.75–3.92) contains standards for the humane handling, care, treatment, and transportation of nonhuman primates.

Section 3.81 of the AWA regulations requires research facilities that house nonhuman primates to develop, document, and follow an appropriate plan for environmental enhancement adequate to promote the psychological well-being of nonhuman primates. The section further specifies that the plan must be in accordance with currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian for the facility. The plan must be available to APHIS upon request, and in the case of research facilities, it must also be available to the funding agency. The plan must address at a minimum: Social grouping, environmental enrichment, special considerations, and use of restraint devices. Exemptions to the plan can be made by the attending veterinarian for the facility because of a particular animal's health or condition, or in consideration of that animal's well-being. Additionally, the Institutional Animal Care and Use Committee (IACUC), a committee entrusted with ensuring the research facility's compliance with the AWA

regulations, may exempt individual nonhuman primates from the plan for scientific reasons, provided these reasons are set forth in a research proposal and reviewed by the IACUC.

On May 7, 2014, APHIS received a petition submitted jointly by the New England Anti-Vivisection Society, the North American Primate Sanctuary Alliance, the Laboratory Primate Advocacy Group, and the Animal Legal Defense Fund requesting that we initiate rulemaking to amend the AWA regulations. Specifically, the petition asks that we amend § 3.81 to require that research facilities construct and maintain an ethologically appropriate environment for nonhuman primates housed at the facilities, that is, an environment that is appropriate with respect to the patterns of behavior exhibited by the nonhuman primates in their natural state. The petition also asks that we amend § 3.81 to specify minimum standards that must be met in order for an environment to be considered ethologically appropriate. The petition cites standards recently adopted by the National Institutes of Health (NIH) for chimpanzees used in NIH-funded research as a reference point for the development of such generally applicable minimum standards and as evidence of their feasibility.

The petition agrees that the intent of § 3.81 of the AWA regulations is to ensure that the environment provided to nonhuman primates housed at research facilities promotes the psychological well-being of the primates. The petition suggests, however, that because of ambiguities in the current regulations, research facilities have broad discretion regarding the actual environment provided to nonhuman primates at their facilities, and can meet the requirements in § 3.81 without actually meeting their intent.

The petition states that, by amending the AWA regulations in the manner that the petitioners suggest, we would remove these ambiguities and facilitate regulatory compliance.

We are making this petition available to the public and soliciting comments to help determine what action, if any, to take in response to this request. The petition and any comments submitted are available for review as indicated under **ADDRESSES** above. We welcome all comments on the issues outlined in the petition. In particular, we invite responses to the following questions:

1. Should APHIS amend § 3.81 of the AWA regulations to require research facilities to construct and maintain an ethologically appropriate environment for nonhuman primates, and specify the minimum standards that must be met for an environment to be considered ethologically appropriate?

2. What constitutes an ethologically appropriate environment for a nonhuman primate? Does this differ among species of nonhuman primates? If so, how does it differ?

3. Are there any environmental conditions that make an environment ethologically inappropriate for a nonhuman primate? If so, what are they? Do they differ among species of nonhuman primates?

4. Does an ethologically appropriate environment for nonhuman primates used in research differ from an ethologically appropriate environment for nonhuman primates that are sold or exhibited? If so, in what ways does it differ?

5. Who should make the determination regarding the ethological appropriateness of the environment for nonhuman primates at a particular research facility: The attending veterinarian for the facility, APHIS, or both parties? If both parties should jointly make such a determination, which responsibilities should fall to the attending veterinarian and which to APHIS?

We encourage the submission of scientific data, studies, or research to support your comments and position. We also invite data on the costs and benefits associated with any recommendations. We will consider all comments and recommendations received.

**Authority:** 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 27th day of April 2015.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015–10195 Filed 4–30–15; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF ENERGY

### 10 CFR Part 431

**[Docket No. EERE–2013–BT–STD–0006]**

**RIN 1904–AC55**

## Energy Conservation Standards for Commercial and Industrial Fans and Blowers: Availability of Provisional Analysis Tools

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

**ACTION:** Notice of Data Availability.

**SUMMARY:** The U.S. Department of Energy (DOE) has completed a provisional analysis of the potential economic impacts and energy savings that could result from promulgating an energy conservation standard for commercial and industrial fans and blowers. This analysis incorporates information and comments received after the completion of an analysis presented in a notice of data availability (NODA) published in December 2014. At this time, DOE is not proposing an energy conservation standard for commercial and industrial fans and blowers. This analysis may be used in support of the Appliance Standards Federal Rulemaking Advisory Committee (ASRAC) commercial and industrial fans working group negotiations to develop a recommendation for regulating commercial and industrial fans. DOE encourages stakeholders to provide any additional data or information that may improve the analysis and to present comments submitted to this NODA and to the NODA published in December 2014 to the working group.

**DATES:** Information is available as of May 1, 2015.

**ADDRESSES:** The analysis for this NODA is available at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx?ruleid=25.*

Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by Docket number EERE–2013–BT–STD–0006, by any of the following methods:

(1) *Email:* to *CIFB2013STD0006@ee.doe.gov.* Include EERE–2013–BT–STD–0006 in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.

(2) *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Revisions to Energy Efficiency Enforcement Regulations, EERE–2013–BT–STD–0006, 1000 Independence Avenue SW., Washington, DC 20585–0121. Phone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza SW., Washington, DC 20024. Phone: (202)

586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

(4) *Instructions:* All submissions received must include the agency name and docket number or RIN for this rulemaking.

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

A link to the docket Web page can be found at: *http://www.regulations.gov/#!docketDetail;D=EERE-2013-BT-STD-0006.* The *www.regulations.gov* Web page contains instructions on how to access all documents in the docket, including public comments. See **ADDRESSES**, for further information on how to submit comments through *www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:**

Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–6590. Email: *CIFansBlowers@ee.doe.gov*.

Mr. Peter Cochran, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov*.

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

**SUPPLEMENTARY INFORMATION:**

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## I. History of Energy Conservation Standards Rulemaking for Commercial and Industrial Fans and Blowers

The Energy Policy and Conservation Act of 1975 (EPCA), as amended, established the Energy Conservation Program for Certain Industrial Equipment under Title III, Part C. (42 U.S.C. 6311–6317, as codified) [1] Included among the various types of industrial equipment addressed by EPCA are commercial and industrial fans and blowers, the subject of this notice. (42 U.S.C. 6311(2) (A)) All references to EPCA refer to the statute as amended through the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112–210 (December 18, 2012).

DOE initiated the current rulemaking by publishing a proposed coverage determination for commercial and industrial fans and blowers. 76 FR 37678 (June 28, 2011). This was followed by the publication of a Notice of Public Meeting and Availability of the Framework Document for commercial and industrial fans and blowers in the **Federal Register**. In the Framework Document, DOE requested feedback from interested parties on many issues related to analyses DOE would conduct as part of the rulemaking, such as the engineering analysis, the manufacturer impact analysis (MIA), the life-cycle cost (LCC) and payback period (PBP) analyses, and the national impact analysis (NIA). 78 FR 7306 (February 1, 2013).[2]

On December 10, 2014, DOE published a Notice of Data Availability (the ''December 2014 NODA'') that presented a provisional analysis estimating the potential economic impacts and energy savings that could result from promulgating a regulatory energy conservation standard for commercial and industrial fans and blowers. 79 FR 73246.[3] The December 2014 NODA analysis relied on an electric input power based metric (*i.e.,* ''wire-to-air''), the fan energy index (FEI). The FEI of a fan was defined as the average electric input power, or fan energy rating, of a fan that exactly meets the efficiency level being analyzed ($FER_{STD}$), divided by the average electric input power or fan energy rating of the fan (FER). In the December 2014 NODA, the FER was calculated over a specific load profile based on the fan's flow at peak total efficiency [4] and at a specified speed.[5]

In October 2014, several energy efficiency advocates and representatives of fan manufacturers [6] (the ''Joint Stakeholders'') presented a different energy metric approach to DOE called ''Fan Efficiency Ratio''. The Joint Stakeholder approach included a fan efficiency only metric ($FER_H$) as well as a wire-to-air metric ($FER_W$).[7] This metric approach was described in more details by AMCA in a white paper (''AMCA white paper'') published in December 2014 which AMCA included in comments to the December 2014 NODA.[8] (AMCA, No. 48 at p. 15) Based on the additional information received, and comments to the December 2014 NODA, DOE revised its analysis. This second NODA presents an analysis that characterizes fan performance and efficiency levels using a revised FEI metric that is based on the $FER_W$ presented by the Joint Stakeholders. (See section III.A for details on the revised FEI metric)

## II. Current Status

The analyses described in this NODA were developed to support a potential energy conservation standard for commercial and industrial fans. As DOE announced in an April 2015 notice, DOE intends to establish a negotiated rulemaking working group under the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC) in accordance with the Federal Advisory Committee Act (FACA) and the Negotiated Rulemaking Act (NRA) to negotiate proposed definitions, the equipment classes for which standards would be considered (including any system interaction effects), certain aspects of a proposed test procedure (if

[1] For editorial reasons, upon codification in the U.S. Code, Part C was re-designated Part A–1.

[2] Supporting documents are available at: *http://www.regulations.gov/#!docketDetail;D=EERE-2013-BT-STD-0006*

[3] The December 2014 NODA comment period was originally scheduled to close on January 26, 2015. DOE subsequently published a notice in the **Federal Register** extending the comment period to February 25, 2015, to allow additional time for interested parties to submit comments.

[4] The efficiency of a fan is defined as the ratio of air output power to mechanical input power. Fan efficiency varies depending on the output flow and pressure. The best efficiency point or BEP represents the flow and pressure values at which the fan efficiency is maximized when operating at a given speed.

[5] In the December 2014 NODA, DOE calculated the FEI at the speed corresponding to the highest electric motor synchronous speed configuration that exists within the fan's operational speed range.

[6] The Air Movement and Control Association (AMCA), New York Blower Company, Natural Resources Defense Council (NRDC), the Appliance Standards Awareness Project (ASAP), and the Northwest Energy Efficiency Alliance (NEEA).

[7] Supporting documents from this meeting, including presentation slides are available at: *http://www.regulations.gov/#a!documentDetail;D=EERE-2013-BT-STD-0006-0029.*

[8] All comments are available at: *http://www.regulations.gov/#!docketDetail;D=EERE-2013-BT-STD-0006.*

applicable), and proposed energy conservation standards for fans and blowers. 80 FR 17359 (April 1, 2015)

To examine these issues, and others as necessary, DOE will provide to all parties in the negotiation data and an analytic framework complete and accurate enough to support their deliberations. DOE is publishing this analysis to inform a prospective negotiation.

In this NODA, DOE is not proposing any energy conservation standards for commercial and industrial fans. DOE may revise the analyses presented in this NODA based on any new or updated information or data it obtains during the course of the rulemaking. DOE encourages stakeholders to provide any additional data or information that may improve the analysis.

## III. Summary of the Analyses Performed by DOE

DOE developed a fan energy performance metric and conducted provisional analyses of commercial and industrial fans in the following areas: (1) Engineering; (2) manufacturer impacts; (3) LCC and PBP; and (4) national impacts. The metric and provisional analyses incorporate information received after the completion of the analysis for the December 2014 NODA, including the published fan industry white paper ''Fan Efficiency Ratios'' and a database of confidential sales information provided by (AMCA). The fan energy performance metric and the tools used in preparing these analyses and their respective results are available at: *http://www.regulations.gov/#!docketDetail;D=EERE-2013-BT-STD-0006.* Each individual spreadsheet includes an introduction that provides an overview of the contents of the spreadsheet. These spreadsheets present the various inputs and outputs to the analysis and, where necessary, instructions. Brief descriptions of the fan energy performance metric, of the provisional analyses, and of the supporting spreadsheet tools are provided below. If DOE proposes an energy conservation standard for commercial and industrial fans in a future NOPR, then DOE will publish a TSD containing a detailed written account of the analyses performed in support of the NOPR, which will include updates to the analyses made available in this NODA.

### *A. Energy Metric*

Commercial and industrial fan energy performance is a critical input in the provisional analyses discussed in this notice. For the purpose of this NODA, DOE revised the fan energy metric used to represent fan performance and characterize the efficiency levels analyzed in the December 2014 NODA. The revised FEI metric is based on an approach similar to the wire-to-air metric presented by the Joint Stakeholders to DOE in October 2014. AMCA subsequently published a white paper in December 2014 that describes the Joint Stakeholder approach in more detail. AMCA included this white paper in its publicily-available comments to the December 2014 NODA, which additional stakeholders supported in their written comments on the December 2014 NODA.[9] [10] (Joint Stakeholders, No. 50 at p. 2; AMCA, No. 48 at p. 15; CAIous, No. 49 at p. 2; Morrison, No. 51 at p. 2)

In this NODA, the FEI is defined as the electric input power of a fan, or fan energy rating that exactly meets the efficiency level being analyzed ($FER_{STD}$), divided by the electric input power, or fan energy rating, of a given fan model (FER) at a given operating point (characterized by a value of flow and total pressure). For a given operating point, an FEI value less than one would indicate that the fan does not meet the efficiency level being analyzed for that given operating point, while a value greater than one would indicate that the fan is more efficient than the efficiency level being analyzed at that given operating point. For each fan operating point, the FEI is calculated as:

$$FEI = \frac{FER_{STD}}{FER}$$

In order to calculate the FER of a fan, DOE assumed default motor full load and part load efficiency values, as well as default transmission losses:[11]

$$FER_i = \frac{Q_i \times P_i}{\eta_{fan,i} \times 6343 \times \eta_{T,i}} + L_{M,i} = \frac{BHP_i}{\eta_{T,i}} + L_{M,i}$$

Where:

$FER_i$: electrical input power (hp) at operating point i;

$Q_i$: flow (cfm) at operating point i;

$P_i$: total fan efficiency (%) at operating point i;

$\eta_{fan,i}$: total fan efficiency (%) at operating point i;

$\eta_{T,i}$: default transmission efficiency (%) at oprating point i (equals 100% f the fan is a direct driven fan);

$L_{M,i}$: default electric motor losses (hp) at operatin gpoint i;

$BHP_i$: shaft input power (hp) at operating point i;

6343: conversion factor to I–P units.

For the $FER_{STD}$ calculation of a fan that exactly meets the efficiency level being analyzed, DOE used the same FER equation, except the calculation of the fan shaft input power is based on a minimum allowable fan total efficiency:

$$FER_{STD,i} = \frac{Q_i \times P_i}{\eta_{STD,i} \times 6343 \times \eta_{T,i}} + L_{M,i} = \frac{BHP_{STD,i}}{\eta_{T,i}} + L_{M,i}$$

Where:

$FER_{STD,i}$: Maximum allowable electrical input power (hp) at operating point i;

$BHP_{STD,i}$: Maximum allowable shaft input power (hp) at operating point i;

$Q_i$: flow (cfm) at operating point i;

$P_i$: total pressure (in.wg) at operating point i;

$\eta_{STD,i}$: minimum total fan efficiency (%) at operating point i ;

$\eta_{T,i}$: default transmission efficiency (%) at operating point i (the minimally

[9] Supporting documents from the October 2014 meeting, including presentation slides are available at: *http://www.regulations.gov/#!documentDetail;D=EERE-2013-BT-STD-0006-0029.*

[10] *AMCA, Introducing Fan Efficiency Ratios,* December 2014, *http://www.amca.org/resources/FER_Whitepaper_single%20pages.pdf.*

[11] These default losses assumptions are presented in the LCC spreadsheet, in the ''Default Losses'' worksheet. The default transmission efficiency is equal to one in case of a direct driven fan.

compliant fan is assumed to always be belt-driven);

$L_{M,i}$: default electric motor losses (hp) at operating point i;

6343: conversion factor to I–P units.

For all fan categories, the minimum fan total efficiency at a given operating point is expressed as a function of flow and total pressure, as follows:

$$\eta_{STD,i} = \eta_{target} \frac{Q_i \times P_i}{(Q_i + Q_0)(P_i + P_0)} = \frac{Q_i \times P_i}{BHP_{STD,i} \times 6343}$$

Where:

$\eta_{STD,i}$: Minimum total fan efficiency (%) at operating point i;

$BHP_{STD,i}$: Max allowable shaft input power (hp) at operating point i;

$Q_0$: flow constant equal to 250

$P_0$: total pressure constant equal to 0.4

$\eta_{target}$: constant used to establish the efficiency level [12]

6343: conversion factor to I–P units

This equation was based on the metric approach recommended by the Joint Stakeholders as well as on AMCA's proposed values for $Q_0$ and $P_0$ and on DOE's preliminary review of the applicability of this equation.[13]

The primary difference between the revised FEI metric used in this NODA and the wire-to-air metric recommended by the Joint Stakeholders is that the Joint Stakeholders recommend using an equation expressing static efficiency [14] as a function of static pressure and flow when calculating FER and $FER_{STD}$ at a given operating point for unducted fans (*i.e.* fans generally applied without a duct on their outlet), instead of using total efficiency as a function of total pressure and flow, as recommended for ducted fans.[15] In its white paper, AMCA states that a metric based on static efficiency should be used for unducted fans, to accommodate the selection of unducted fans based on the use of static pressure. AMCA noted, however, that this opinion is not shared across all the industry. Three additional representatives of the industry agreed that static efficiency should be the basis for any metric related to unducted fans because of existing selection practices, while one recommended using total efficiency for all fan categories. (Joint Stakeholders, No. 50 at p. 3; AMCA, No. 48 at p. 16; CES Group LLC, No. 40 at p. 1; Multi-wing, No. 52 at p. 2; Carrier, No. 43 at p. 6; Morrison, No. 51 at p. 2)

DOE understands that using static pressure may be useful for selecting unducted fans, however, because static efficiency is, by definition, calculated using total pressure, and because the shaft input power of a fan is a function of the fan's total output power and total efficiency, DOE maintained the use of an energy metric based on total pressure and total efficiency for all fan categories.[16] DOE does not believe this approach would prevent end-users from selecting fans using either static or total pressure.

*B. Engineering Analysis*

The engineering analysis establishes the relationship between the manufacturer production cost (MPC) and efficiency levels of commercial and industrial fans and blowers. This relationship serves as the basis for calculations performed in the other analysis tools to estimate the costs and benefits to individual consumers, manufacturers, and the nation.

As a first step in the engineering analysis, DOE established seven provisional fan groups based on characteristics such as the direction of airflow through the fan and the presence of a housing. While DOE analyzed seven provisional fan groups in this NODA, DOE expects the working group to discuss and ultimately recommend equipment classes for which standards would be considered. For each of the seven provisional fan groupings, DOE identified existing technology options that could affect efficiency. DOE then conducted a screening analysis to review each technology option and decide whether it: (1) Is technologically feasible; (2) is practicable to manufacture, install, and service; (3) would adversely affect product utility or product availability; or (4) would have adverse impacts on health and safety. The technology options remaining after the screening analysis consisted of a variety of impeller types and guide vanes. DOE used these technology options to divide the fan groups into subgroups and conducted a market-based assessment of the prevalence of each subgroup at the different efficiency levels analyzed using the sales data provided by AMCA. This NODA has fewer subgroups than the December 2014 NODA due to limitations in the sales data provided by AMCA. DOE analyzed six efficiency levels in this NODA, each representing a different efficiency target ($\eta_{target}$). AMCA presented results for an efficiency target of 62 percent for ducted fans.[17] This NODA includes one efficiency level representing the same efficiency target as well as additional levels above and below.

DOE estimated the MPCs for each technology option for each fan group as a function of blade or impeller diameter, independent of efficiency level. DOE then calculated MPCs for each fan group at each efficiency level analyzed by weighting the MPCs of each technology option within a group by its prevalence at the efficiency level being analyzed. The MPCs were derived from product teardowns and publically-available product literature and informed by interviews with manufacturers.

DOE's preliminary MPC estimates indicate that the changes in MPC as efficiency level increases are small or, in some fan groups, zero. However, DOE is aware that aerodynamic redesigns are a primary method by which manufacturers improve fan performance. These redesigns require manufacturers to make large upfront investments for R&D, testing and prototyping, and purchasing new production equipment. DOE's preliminary findings indicate that the magnitude of these upfront costs is more significant than the difference in MPC of a fan redesigned for efficiency compared to its precursor. For this NODA, DOE included a conversion cost markup in its calculation of the manufacturer selling price (MSP) to account for these

[12] The efficiency target is a constant that described the expected minimum allowable fan efficiency for very high flow and total pressure operating points at a given efficiency level.

[13] See AMCA's DOE Fan efficiency Proposal presented at the 59th AMCA Annual Meeting, January 24, 2015. *http://www.amca.org/adovacy/documents/DOEFanEfficiencyProposal-AMCAAnnualMeetingRedux1-24-15.pdf.*

[14] Static efficiency is equal to the total efficiency multiplied by the ratio of static pressure to total pressure, at a given point of operation. Static pressure is the difference between fan total pressure and fan velocity pressure at a given point of operation.

[15] Unducted fans include the following fan categories: Axial unhoused, centrifugal unhoused, and power roof ventilators.

[16] The fan's total output power is the power delivered to the air (or gas). It is proportional to the product of the fan airflow rate and fan total pressure (if air were incompressible).

[17] See AMCA's DOE Fan efficiency Proposal presented at the 59th AMCA Annual Meeting, January 24, 2015. *http://www.amca.org/adovacy/documents/DOEFanEfficiencyProposal-AMCAAnnualMeetingRedux1-24-15.pdf*

conversion costs. These markups and associated MSPs were developed and applied in downstream analyses. They are discussed in section C and presented in the engineering analysis and conversion cost spreadsheet.

The main outputs of the commercial and industrial fans engineering analysis are the MPCs of each fan group (including material, labor, and overhead) and technology option distributions at each efficiency level analyzed.

*C. Manufacturer Impact Analysis*

For the MIA, DOE used the Government Regulatory Impact Model (GRIM) to assess the economic impact of potential standards on commercial and industrial fan manufacturers. DOE developed key industry average financial parameters for the GRIM using publicly available data from corporate annual reports along with information received through confidential interviews with manufacturers. These values include average industry tax rate; working capital rate; net property, plant, and equipment rate; selling, general, and administrative expense rate; research and development expense rate; depreciation rate; capital expenditure rate; and manufacturer discount rate.

Additionally, DOE calculated total industry capital and product conversion costs associated with meeting all analyzed efficiency levels. DOE first estimated the average industry capital and product conversion costs associated with redesigning a single fan model to meet a specific efficiency level. DOE estimated these costs for all technology options within each fan group. DOE multiplied the per model conversion costs by the number of models that would be required to be redesigned at each potential standard level to arrive at the total industry conversion costs. The number of models that would be redesigned was calculated using information from the AMCA sales database.

In the December 2014 NODA, DOE assumed a redesign time of six months and an additional testing time of six months. Five representatives of the industry commented that six months was not a representative redesign time and made recommendations ranging from 12 to 24 months. (AHRI, No. 53 at p. 8; AMCA, No. 48 at p. 4; Carrier, No. 43 at p. 2; Greenheck, No. 54 at p. 5; Morrison, No. 51 at p. 4) DOE revised its conversion cost estimates in this NODA to assume a redesign time of 12 months and additional testing time of 6 months.

The GRIM uses these estimated values in conjunction with inputs from other analyses including the MPCs from the engineering analysis, the annual shipments by fan group from the NIA, and the manufacturer markups for the cost recovery markup scenario from the LCC analysis to model industry annual cash flows from the base year through the end of the analysis period. The primary quantitative output of this model is the industry net present value (INPV), which DOE calculates as the sum of industry annual cash flows, discounted to the present day using the industry specific weighted average cost of capital, or manufacturer discount rate.

Standards can affect INPV in several ways including requiring upfront investments in manufacturing capital as well as research and development expenses, which increase the cost of production and potentially alter manufacturer markups. DOE expects that manufacturers may lose a portion of INPV due to standards. The potential loss in INPV due to standards is calculated as the difference between INPV in the base-case (absent new energy conservation standards) and the INPV in the standards case (with new energy conservation standards in effect). DOE examines a range of possible impacts on industry by modeling various pricing strategies commercial and industrial fan manufacturers may adopt following the adoption of new energy conservations standards for commercial and industrial fans.

In addition to INPV, the MIA also calculates the manufacturer markups, which are applied to the MPCs derived in the engineering analysis, to arrive at the manufacturer selling prices (MSPs) in the base case. For efficiency levels above the baseline, which require manufacturers to redesign models that do not meet the potential standards, conversion cost recovery markups were incorporated into the MSP in addition to the manufacturer markup. These conversion markups are based on the total conversion costs from the MIA and calculated to allow manufacturers to recover their upfront conversion costs. They are calculated by amortizing the conversion investment over the units shipped throughout the analysis period that were redesigned to meet the efficiency level being analyzed. The base case and standards case MSPs were used as inputs for downstream analyses.

*D. Life-Cycle Cost and Payback Period Analyses*

The LCC and PBP analyses determine the economic impact of potential standards on individual consumers, in the compliance year. The LCC is the total cost of purchasing, installing and operating a commercial or industrial fan over the course of its lifetime.

DOE determines the LCC by considering: (1) The total installed cost to the consumer (which consists of manufacturer selling price, distribution channel markups, and sales taxes); (2) the range of annual energy consumption of commercial and industrial fans as they are used in the field; (3) the operating cost of commercial and industrial fans (*e.g.,* energy cost); (4) equipment lifetime; and (5) a discount rate that reflects the real consumer cost of capital and puts the LCC in present-value terms. The PBP represents the number of years needed to recover the increase in purchase price of higher-efficiency commercial and industrial fans through savings in the operating cost. PBP is calculated by dividing the incremental increase in installed cost of the higher efficiency product, compared to the baseline product, by the annual savings in operating costs.

For each considered standards case corresponding to each efficiency level, DOE measures the change in LCC relative to the base case. The base case is characterized by the distribution of equipment efficiencies in the absence of new standards (*i.e.,* what consumers would have purchased in the compliance year in the absence of new standards). In the standards cases, equipment with efficiency below the standard levels ''roll-up'' to the standard level in the compliance year.

To characterize annual fan operating hours, DOE established statistical distributions of consumers of each fan category across sectors (industry or commercial) and applications (clean air ventilation, exhaust, combustion, drying, process air, process heating/cooling, and others), which in turn determined the fan's operating hours. Recognizing that several inputs to the determination of consumer LCC and PBP are either variable or uncertain (*e.g.,* annual energy consumption, lifetime, discount rate), DOE conducts the LCC and PBP analysis by modeling both the uncertainty and variability in the inputs using Monte Carlo simulations and probability distributions.

In addition to characterizing several of the inputs to the analyses with probability distributions, DOE developed a sample of individual fan selections (*i.e.,* a fan models and the operating flow and pressure values for which they were purchased) using fan sales data provided by AMCA [18]. By

[18] See description in LCC spreadsheet, LCC sample description worksheet.

developing this sample, DOE was able to perform the LCC and PBP calculations for each fan selection to account for the variability in energy consumption associated with each fan selection. DOE notes that when developing the LCC sample, it did not include fan sales data for which no flow and pressure selection information was available.

The primary outputs of the LCC and PBP analyses are: (1) Average LCC in each standards case; (2) average PBPs; (3) average LCC savings at each standards case relative to the base case; and (4) the percentage of consumers that experience a net benefit, have no impact, or have a net cost for each fan group and efficiency level. The average annual energy consumption derived in the LCC analysis is used as an input in the NIA.

*E. National Impact Analysis*

The NIA estimates the national energy savings (NES) and the net present value (NPV) of total consumer costs and savings expected to result from potential new standards at each EL. DOE calculated NES and NPV for each EL as the difference between a base case forecast (without new standards) and the standards case forecast (with standards). Cumulative energy savings are the sum of the annual NES determined for the lifetime of a commercial or industrial fan shipped during a 30 year analysis period assumed to start in 2019.[19] Energy savings include the full-fuel cycle energy savings (*i.e.*, the energy needed to extract, process, and deliver primary fuel sources such as coal and natural gas, and the conversion and distribution losses of generating electricity from those fuel sources). The NPV is the sum over time of the discounted net savings each year, which consists of the difference between total energy cost savings and increases in total equipment costs. NPV results are reported for discount rates of 3 and 7 percent.

To calculate the NES and NPV, DOE projected future shipments[20] and efficiency distributions (for each EL) for each potential commercial and industrial fan category. DOE recognizes the uncertainty in projecting shipments and electricity prices; as a result the NIA includes several different scenarios for each. Other inputs to the NIA include the estimated commercial and industrial fan lifetime used in the LCC analysis, manufacturer selling prices from the MIA, average annual energy consumption, and efficiency distributions from the LCC.

## IV. Issues on Which DOE Seeks Public Comment

DOE is interested in receiving comment on all aspects of this analysis. DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

1. DOE requests comments on the equation expressing fan total efficiency as presented in this notice, as a function of flow and total pressure.
2. DOE requests comment on the values of the flow constant ($Q_0$) and total pressure constant ($P_0$) used to calculate the minimum fan total efficiency at a given operating point.
3. DOE requests comments on the default transmission efficiency equation used in the FEI calculation.
4. DOE requests comments on the default motor losses assumptions used in the FEI calculation.
5. DOE requests comments on how manufacturers determine/would determine whether to redesign or eliminate a fan model that is not compliant at an operating point or points at which it has been sold previously.
6. DOE estimated the number of redesigns at each efficiency level based on the sales data provided by AMCA. DOE recognizes that the AMCA data does not include all commercial and industrial fan sales for the industry, and that existing fans can operate at more selection points than those at which they were sold as represented in the AMCA sales database. DOE requests comments on whether the resulting total conversion costs presented in the spreadsheets released with this NODA are representative of the industry at the efficiency levels analyzed. If not, how should the number of redesigns be adjusted to be representative of the industry?
7. DOE requests additional information to allow quantifying installation, repair, and maintenance costs for industrial and commercial fans.
8. DOE requests additional information to allow quantifying lifetimes for industrial and commercial fans.
9. DOE requests additional information to allow quantifying annual operating hours for industrial and commercial fans.
10. DOE seeks inputs and comments on the estimates of flow and total pressure operating points used in the energy use analysis.
11. DOE requests comments on how to account for consumers purchasing fans without providing any selection data (*i.e.,* design flow and pressure values) in the LCC calculations.
12. DOE requests comment on determining the motor horsepower based on 120 percent of the fan shaft input power when performing the energy use calculation.
13. DOE requests comments on the method used in the LCC to identify fans that could be considered substitutes.
14. DOE seeks comments and inputs regarding the use of typical fan curves and efficiency curves in order to calculate fan shaft input power at different flow and pressure values based on a fan selection's performance data at a single given design point.
15. DOE seeks inputs to support the development of trends in fan efficiency over time in the base case and in the standards cases.

The purpose of this NODA is to notify industry, manufacturers, consumer groups, efficiency advocates, government agencies, and other stakeholders of the publication of an analysis of potential energy conservation standards for commercial and industrial fans. Stakeholders should contact DOE for any additional information pertaining to the analyses performed for this NODA.

Issued in Washington, DC, on April 21, 2015.

**Kathleen B. Hogan,**

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

[FR Doc. 2015–10036 Filed 4–30–15; 8:45 am]

**BILLING CODE 6450–01–P**

[19] The LCC and NIA spreadsheet provide results for a different compliance year (2019, 2020, and 2021).

[20] The ''shipments'' worksheet of the NIA spreadsheet presents the scope of the analysis and the total shipments value in units for the fans in scope.

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## SMALL BUSINESS ADMINISTRATION

### 13 CFR Part 127

**RIN 3245–AG72**

### Women-Owned Small Business Federal Contract Program

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The U.S. Small Business Administration (SBA) proposes to amend its regulations to implement section 825 of the National Defense Authorization Act for Fiscal Year 2015 (2015 NDAA). Section 825 of the 2015 NDAA included language granting contracting officers the authority to award sole source contracts to Women-

Owned Small Businesses (WOSBs) and Economically Disadvantaged Women-Owned Small Businesses (EDWOSBs). Section 825 of the 2015 NDAA also changed the deadline for SBA to conduct a study to determine the industries in which WOSBs are underrepresented to January 2, 2016. As a result, SBA is proposing to amend its definitions of underrepresentation and substantial underrepresentation.

**DATES:** Comments must be received on or before June 30, 2015.

**ADDRESSES:** You may submit comments, identified by RIN: 3245–AG72, or by docket number SBA–2015–0004, by any of the following methods: (1) Federal Rulemaking Portal: *http://www.regulations.gov* and follow the instructions for submitting comments; or (2) Mail/Hand Delivery/Courier: Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning & Liaison, 409 Third Street SW., 8th Floor, Washington, DC 20416. SBA will not accept comments to this proposed rule submitted by email. SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW., 8th Floor, Washington, DC 20416, or send an email to *brenda.fernandez@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

**FOR FURTHER INFORMATION CONTACT:** Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning & Liaison, 409 Third Street SW., 8th Floor, Washington, DC 20416; (202) 205–7337; *brenda.fernandez@sba.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Women-Owned Small Business (WOSB) Program, set forth in section 8(m) of the Small Business Act, 15 U.S.C. 637(m), authorizes Federal contracting officers to restrict competition to eligible Women-Owned Small Businesses (WOSBs) or Economically Disadvantaged Women-Owned Small Businesses (EDWOSBs) for Federal contracts in certain industries. Section 8(m) of the Small Business Act (Act) sets forth certain criteria for the WOSB Program, including the eligibility and contract requirements for the program. Congress recently amended the WOSB Program with section 825 of the National Defense Authorization Act for Fiscal Year 2015, Public Law 113–291, 128 Stat. 3292 (December 19, 2014) (2015 NDAA), which included language granting contracting officers the authority to award sole source awards to WOSBs and EDWOSBs and shortening the time period for SBA to conduct a required study to determine the industries in which WOSBs are underrepresented.

## II. Section-by-Section Analysis

### *A. Sole Source Authority*

In order to implement these statutory changes, SBA is proposing to amend 13 CFR part 127. Specifically, this proposed rule amends § 127.101, concerning the type of contracting assistance available under part 127, to include the new sole source authority. This proposed rule also amends the definitions of the terms ''EDWOSB requirement'' and ''WOSB requirement'' in § 127.102 to include sole source contracts. The proposed rule also amends § 127.500, which concerns the industries in which a contracting officer is authorized to restrict competition under the WOSB program, to address the new sole source authority.

SBA proposes to amend § 127.503 by adding two new paragraphs to incorporate the statutory language of section 825 of the 2015 NDAA granting authority for sole source contracts to EDWOSBs and WOSBs. Under this statutory authority, if a contracting officer conducts market research in an industry where a WOSB or EDWOSB set-aside is authorized, and the contracting officer cannot identify two or more WOSBs or EDWOSBs that can perform at a fair and reasonable price, but identifies one WOSB or EDWOSB that can perform at a fair and reasonable price, the contracting officer can award the contract on a sole source basis, if the value of the contract, including options, does not exceed $6.5 million for manufacturing contracts and $4 million for all other contracts.

The proposed rule also amends § 127.507, concerning contracting opportunities at or below the simplified acquisition threshold, to address sole source awards under the WOSB Program. Finally, the proposed rule amends the protest regulations in § 127.600 to include procedures for protests involving sole source contracts. The protest procedures for sole source contracts to WOSBs and EDWOSBs would be the same as those procedures for sole source contracts involving service-disabled veteran owned small business concerns (SDVO SBC) (§ 125.24(a)) and HUBZone small business concerns (§ 126.800(a)).

### *B. Time Period for Study*

In order to comply with the revised timeline for SBA to conduct a required study to determine the industries in which WOSBs are underrepresented, SBA is proposing to revise the definitions of ''underrepresentation'' and ''substantial underrepresentation'' in § 127.102. Section 825 established a new timeline for SBA to conduct a study to determine the industries in which WOSBs are underrepresented. The original deadline for this study was established by section 1697(b) of the National Defense Authorization Act of 2013, Pub. L. 112–239, January 2, 2013, 126 Stat. 2091 (2013 NDAA), which required SBA to conduct a study of the industries in which WOSBs are underrepresented within five years of the date of enactment of the 2013 NDAA (and every 5 years thereafter). Section 825 of the 2015 NDAA amended section 1697(b) of the 2013 NDAA and changed the deadline to within 3 years of the date of enactment of the 2013 NDAA, which means the study must be conducted by January 2, 2016.

In order to meet this deadline, the proposed rule amends the definitions of the terms ''substantial underrepresentation'' and ''underrepresentation'' in § 127.102. This change would allow SBA to conduct a study within the time constraint imposed by Congress by providing SBA with the flexibility necessary to conduct the most reliable and relevant study of WOSB participation in Federal contracting. In addition, the new definitions of these terms would align more closely than the current definitions with the statutory intent of the 2013 NDAA and the 2015 NDAA.

### *C. Other*

SBA recognizes that Section 825 also created a requirement that a firm be certified as a WOSB or EDWOSB by a Federal Agency, a State government, SBA, or a national certifying entity approved by SBA. This statutory requirement appears to apply to both sole source and set asides under the WOSB Program, and may require substantial resources. Establishing a certification requirement and process will require a more prolonged rulemaking before SBA can establish such a program. In our view, there is no evidence that Congress intended to halt the existing WOSB Program until such time as SBA establishes the

infrastructure and issues regulations implementing the statutory certification requirement. Instead, we maintain that the new WOSB sole source authority can and should be implemented as quickly as possible, using existing program rules and procedures, while SBA proceeds with implementing the certification requirement through a separate rulemaking.

## III. Compliance With Executive Orders 12866, 12988, 13132, 13563, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

*Executive Order 12866*

The Office of Management and Budget (OMB) has determined that this rule does not constitute a significant regulatory action under Executive Order 12866. This is not a major rule under the Congressional Review Act (CRA), 5 U.S.C. 800.

*Executive Order 12988*

This action meets applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

*Executive Order 13132*

For the purpose of Executive Order 13132, SBA has determined that the proposed rule 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. Therefore SBA has determined that this proposed rule has no federalism implications warranting the preparation of a federalism assessment.

*Executive Order 13563*

A description of the need for this regulatory action, the benefits and costs associated with this action, and any alternatives are included in the Initial Regulatory Flexibility Analysis.

In drafting this proposed rule, SBA considered input submitted by three coalitions of women's groups representing women-owned small businesses who support this rule and encourage its quick implementation.

*Paperwork Reduction Act, 44 U.S.C., Ch. 35*

For the purpose of the Paperwork Reduction Act, 44 U.S.C., Chapter 35, SBA has determined that this proposed rule does not impose additional reporting or recordkeeping requirements.

*Regulatory Flexibility Act, 5 U.S.C., 601–612*

According to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601, when an agency issues a rulemaking, it must prepare a regulatory flexibility analysis to address the impact of the rule on small entities. In accordance with this requirement, SBA has prepared an Initial Regulatory Flexibility Analysis addressing the impact of this rule.

*Initial Regulatory Flexibility Analysis*

1. What are the need for and objective of this proposed rule?

This proposed rule is necessary to implement Section 825 of the National Defense Authorization Act for Fiscal Year 2015, Public Law 113–291, December 19, 2014, 128 Stat. 3292 (2015 NDAA). Section 825 of the 2015 NDAA included language granting contracting officers the authority to award sole source contracts to Women-Owned Small Businesses (WOSBs) and Economically Disadvantaged Women-Owned Small Businesses (EDWOSBs). The purpose of this rule is to establish the procedures whereby Federal agencies may award sole source contracts to WOSBs and EDWOSBs and to provide a mechanism to protest such awards. The rule provides an additional tool for Federal agencies to ensure that WOSBs have an equal opportunity to participate in Federal contracting and ensures consistency among SBA's socio-economic small business contracting programs. The objectives of this proposed rule are to put the WOSB Program on a level playing field with other SBA government contracting programs with sole source authority, and to provide an additional, needed tool for agencies to meet the statutorily mandated 5% prime contracting goal for WOSBs.

Section 825 of the 2015 NDAA also revised the timeline for SBA to conduct a study to determine the industries in which WOSBs are underrepresented. This proposed rule is necessary to allow SBA to conduct the most reliable and relevant study of WOSB participation in Federal contracting and comply with the new statutorily mandated timeline.

2. What is the legal basis for this proposed rule?

The legal basis for this proposed rule is section 825 of the National Defense Authorization Act for Fiscal Year 2015, Public Law 113–291, December 19, 2014, 128 Stat. 3292, which amended Section 8(m) of the Small Business Act, 15 U.S.C. 637(m).

3. What is SBA's description and estimate of the number of small entities to which the rule will apply?

The RFA directs agencies to provide a description, and where feasible, an estimate of the number of small business concerns that may be affected by the rule. This proposed rule establishes a new procurement mechanism to benefit WOSBs. Therefore, WOSBs and EDWOSBs available to compete for Federal contracts under the WOSB Program are the specific group of small business concerns most directly affected by this rule.

SBA searched the Dynamic Small Business Supplemental Search (DSBS) and determined that there were approximately 34,000 firms listed as either WOSBs or EDWOSBs under the WOSB Program. In addition, according to the fiscal year 2013 small business goaling report, there were a little over 250,000 actions concerning women-owned small businesses and the total dollar value of those actions was approximately $15 billion. An analysis of the Federal Procurement Data System from April 1, 2011 (the implementation date of the WOSB Program) through January 1, 2013, revealed that there were approximately 26,712 women-owned small business concerns, including 131 EDWOSBs and 388 WOSBs eligible under the WOSB Program, that received obligated funds from Federal contract awards, task or delivery orders, and modifications to existing contracts.

Therefore, this rule could affect a smaller number of EDWOSBs and WOSBs than those eligible under the WOSB Program. We note that the sole source authority can only be used where a contracting officer conducts market research in an industry where a WOSB or EDWOSB set-aside is authorized, and the contracting officer cannot identify two or more WOSBs or EDWOSBs that can perform at a fair and reasonable price, but identifies one WOSB or EDWOSB that can perform. In addition, the sole source authority for WOSBs and EDWOSBs is limited to contracts valued at $6.5 million or less for manufacturing contracts and $4 million or less for all other contracts.

Nonetheless, we believe that this rule may have a significant positive economic impact on EDWOSB concerns competing for Federal contracting opportunities in industries determined by SBA to be underrepresented by WOSB concerns and likewise may positively affect WOSB concerns

eligible under the WOSB Program competing in industries determined by SBA to be substantially underrepresented by WOSB concerns, since the sole source authority will still provide greater access to Federal contracting opportunities.

4. What are the projected reporting, recordkeeping, Paperwork Reduction Act, and other compliance requirements?

SBA has determined that this rule does not impose additional reporting or recordkeeping requirements.

5. What relevant Federal rules may duplicate, overlap, or conflict with this rule?

SBA has not identified any relevant Federal rules currently in effect that duplicates this rule. The sole source mechanism of the WOSB program will be an addition to the procurement mechanisms available under the existing small business contracting programs that agencies currently administer, such as the HUBZone Program, the Service-Disabled Veteran-Owned (SDVO) Small Business Program, and the 8(a) Business Development Program. The sole source mechanism for WOSBs and EDWOSBs is only authorized where a contracting officer conducts market research in an industry where a WOSB or EDWOSB set aside is authorized, and the contracting officer cannot identify two or more WOSBs or EDWOSBs that can perform at a fair and reasonable price, but identifies one WOSB or EDWOSB that can perform (and so long as the value of the contract, including options, does not exceed $6.5 million for manufacturing contracts and $4 million for all other contracts). Therefore, the addition of the sole source mechanism for WOSBs and EDWOSBs should complement rather than conflict with the goals of existing small business procurement programs.

SBA believes that the Federal Acquisition Regulations (FAR) will need to be amended to include this authority so that there is no conflict between the SBA's rules and the FAR.

6. What significant alternatives did SBA consider that accomplish the stated objectives and minimize and significant economic impact on small entitiese?

The RFA requires agencies to identify alternatives to the rule in an effort to minimize any significant economic impact of the rule on small entities. The statutory authority for the sole source awards sets forth specific criteria, including dollar value thresholds for the awards. Therefore, the proposed regulations must implement the statutory provisions, and there are no alternatives for these regulations.

**List of Subjects in 13 CFR Part 127**

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA proposes to amend 13 CFR part 127 as follows:

## PART 127—WOMEN-OWNED SMALL BUSINESS FEDERAL CONTRACT PROGRAM

■ 1. The authority for 13 CFR part 127 continues to read as follows:

**Authority:** 15 U.S.C. 632, 634(b)(6), 637(m), and 644.

■ 2. Revise § 127.101 to read as follows:

### § 127.101 What type of assistance is available under this part?

This part authorizes contracting officers to restrict competition or award sole source contracts or orders to eligible Economically Disadvantaged Women-Owned Small Businesses (EDWOSBs) for certain Federal contracts or orders in industries in which the Small Business Administration (SBA) determines that WOSBs are underrepresented in Federal procurement. It also authorizes contracting officers to restrict competition or award sole source contracts or orders to eligible WOSBs for certain Federal contracts or orders in industries in which SBA determines that WOSBs are substantially underrepresented in Federal procurement and has waived the economically disadvantaged requirement.

■ 3. Amend § 127.102 by revising the definitions of the terms ''EDWOSB requirement'', ''Substantial underrepresentation'', ''Underrepresentation'', and ''WOSB requirement'' to read as follows:

### § 127.102 What are the definitions of the terms used in this part?

* * * * *

*EDWOSB requirement* means a Federal requirement for services or supplies for which a contracting officer has restricted competition or awarded a sole source contract or order to eligible EDWOSBs, including Multiple Award Contracts, partial set-asides, reserves, sole source awards, and orders set-aside for EDWOSBs issued against a Multiple Award Contract.

* * * * *

*Substantial underrepresentation* is determined by a study using a reliable and relevant methodology.

* * * * *

*Underrepresentation* is determined by a study using a reliable and relevant methodology.

* * * * *

*WOSB requirement* means a Federal requirement for services or supplies for which a contracting officer has restricted competition or awarded a sole source contract or order to eligible WOSBs, including Multiple Award Contracts, partial set-asides, reserves, sole source awards, and orders set-aside for WOSBs issued against a Multiple Award Contract.

■ 4. Revise § 127.500 to read as follows:

### § 127.500 In what industries is a contracting officer authorized to restrict competition or make a sole source award under this part?

A contracting officer may restrict competition or make a sole source award under this part only in those industries in which SBA has determined that WOSBs are underrepresented or substantially underrepresented in Federal procurement, as specified in § 127.501.

■ 5. Amend § 127.503 as follows:

■ a. Revise section heading;

■ b. Revise paragraph (a) subject heading and paragraph (b) subject heading;

■ c. Redesigne paragraphs (c), (d), (e) and (f) as paragraphs (e), (f), (g) and (h); and

■ d. Add new paragraphs (c) and (d).

The revisions and additions read as follows:

### § 127.503 When is a contracting officer authorized to restrict competition or award a sole source contract or order under this part?

(a) *Competition restricted to EDWOSBs.* * * *

(b) *Competition restricted to WOSBs.* * * *

(c) *Sole source awards to EDWOSBs.* For requirements in industries designated by SBA as underrepresented pursuant to § 127.501, a contracting officer may issue a sole source award to an EDWOSB when the contacting officer determines that:

(1) The EDWOSB is a responsible contractor with respect to performance of the requirement and the contracting officer does not have a reasonable expectation that 2 or more EDWOSBs will submit offers;

(2) The anticipated award price of the contract (including options) will not exceed $6,500,000 in the case of a contract assigned a North American

Industry Classification System (NAICS) code for manufacturing, or $4,000,000 in the case of any other contract opportunity; and

(3) In the estimation of the contracting officer, the award can be made at a fair and reasonable price.

(d) *Sole source awards to WOSBs.* For requirements in industries designated by SBA as substantially underrepresented pursuant to § 127.501, a contracting officer may issue a sole source award to a WOSB when the contacting officer determines that:

(1) The WOSB is a responsible contractor with respect to performance of the requirement and the contracting officer does not have a reasonable expectation that 2 or more WOSBs will submit offers;

(2) The anticipated award price of the contract (including options) will not exceed $6,500,000 in the case of a contract assigned a NAICS code for manufacturing, or $4,000,000 in the case of any other contract opportunity; and

(3) In the estimation of the contracting officer, the award can be made at a fair and reasonable price.

* * * * *

■ 6. Revise § 127.507 to read as follows:

**§ 127.507 Are there EDWOSB and WOSB contracting opportunities at or below the simplified acquisition threshold?**

If the requirement is valued at or below the simplified acquisition threshold, the contracting may set aside the requirement or award the requirement on a sole source basis as set forth in § 127.503.

■ 7. Revise § 127.600 to read as follows:

**§ 127.600 Who may protest the status of a concern as an EDWOSB or WOSB?**

(a) *For sole source procurements.* SBA or the contracting officer may protest the proposed awardee's EDWOSB or WOSB status.

(b) *For all other EDWOSB or WOSB requirements.* An interested party may protest the apparent successful offeror's EDWOSB or WOSB status.

Dated: April 27, 2015.

**Maria Contreras-Sweet,**

*Administrator.*

[FR Doc. 2015–10331 Filed 4–30–15; 8:45 am]

BILLING CODE 8025–01–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2015–0935; Directorate Identifier 2014–NM–243–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 adopt a new airworthiness directive (AD) for certain The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes. This proposed AD was prompted by several reports of chafing of the wire bundles inside the electrical conduit of the forward and aft boost pumps of the numbers 1 and 4 main fuel tanks due to high vibration. These wire bundles can chafe through the wire sleeving into the insulation, exposing the wire conductors. This proposed AD would require replacing the wire bundles inside the electrical conduit of the forward and aft boost pumps of the numbers 1 and 4 main fuel tanks with new, improved wire bundles inserted into conduit liners. We are proposing this AD to prevent chafing of the wire bundles and subsequent arcing between the wiring and the electrical conduit creating an ignition source in the fuel tanks, which could result in a fire and consequent fuel tank explosion.

**DATES:** We must receive comments on this proposed AD by June 15, 2015.

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

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; phone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this 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. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0935.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0935; 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:** Tung Tran, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6505; fax: 425–917–6590; email: *tung.tran@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–0935; Directorate Identifier 2014–NM–243–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

We have received several reports of chafing of the wire bundles inside the

electrical conduit of the forward and aft boost pumps of the numbers 1 and 4 main fuel tanks due to high vibration. These wire bundles can chafe through the wire sleeving into the insulation, exposing the wire conductors. These conditions, if not prevented, could result in arcing between the wiring and the electrical conduit creating an ignition source in the fuel tanks, which could result in a fire and consequent fuel tank explosion.

**Related AD**

AD 2011–15–03, Amendment 39–16750 (76 FR 41659, July 15, 2011), superseded AD 97–26–07, Amendment 39–10250 (62 FR 65352, December 12, 1997), and continues to require repetitive inspections to detect damage of the sleeving and wire bundles of the boost pumps of the numbers 1 and 4 main fuel tanks, and of the auxiliary tank jettison pumps (if installed); replacement of any damaged sleeving with new sleeving; and repair or replacement of any damaged wires with new wires. For airplanes on which any burned wires are found, AD 2011–15–03 also continues to require an inspection to detect damage of the conduit, and replacement of any damaged conduit with a serviceable conduit. AD 2011–15–03 reduced the initial compliance time and repetitive inspection interval in AD 97–26–07. AD 2011–15–03 was prompted by fleet information indicating that the repetitive inspection interval in AD 97–26–07 was too long because excessive chafing of the sleeving continued to occur much earlier than expected between scheduled inspections. Accomplishing the replacement specified in this proposed AD would terminate the repetitive inspections required by paragraph (n) of AD 2011–15–03.

**Related Service Information Under 1 CFR Part 51**

We reviewed Boeing Alert Service Bulletin 747–28A2306, dated October 2, 2014. The service information describes procedures for replacing the wire bundles of the electrical conduit inside the electrical conduit of the forward and aft boost pumps of the numbers 1 and 4 main fuel tanks. This service information is reasonably available at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0935. Or see **ADDRESSES** for other ways to access this service information.

**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 require accomplishing the actions specified in the service information identified previously.

**Costs of Compliance**

We estimate that this proposed AD affects 176 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 |
|---|---|---|---|---|
| Replacement ..... | Up to 53 work-hours × $85 per hour = $4,505 ..... | $4,600 | Up to $9,105 ..... | Up to $1,602,480. |

**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.

**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):

**The Boeing Company:** Docket No. FAA–2015–0935; Directorate Identifier 2014–NM–243–AD.

**(a) Comments Due Date**

We must receive comments by June 15, 2015.

**(b) Affected ADs**

This AD affects AD 2011–15–03, Amendment 39–16750 (76 FR 41659, July 15, 2011).

**(c) Applicability**

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 747–28A2306, dated October 2, 2014.

**(d) Subject**

Air Transport Association (ATA) of America Code 28, Fuel.

**(e) Unsafe Condition**

This AD was prompted by several reports of chafing of the wire bundles inside the electrical conduit of the forward and aft boost pumps of the numbers 1 and 4 main fuel tanks due to high vibration. These wire bundles can chafe through the wire sleeving into the insulation, exposing the wire conductors. We are issuing this AD to prevent chafing of the wire bundles and subsequent arcing between the wiring and the electrical conduit creating an ignition source in the fuel tanks, which could result in a fire and consequent fuel tank explosion.

**(f) Compliance**

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

**(g) Replacement**

Within 60 months after the effective date of this AD: Replace the wire bundles inside the electrical conduit of the forward and aft boost pumps of the numbers 1 and 4 main fuel tanks with new, improved wire bundles inserted into conduit liners, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–28A2306, dated October 2, 2014. Accomplishing the replacement required by this paragraph terminates the repetitive inspections required by paragraph (n) of AD 2011–15–03, Amendment 39–16750 (76 FR 41659, July 15, 2011).

**(h) 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 paragraph (i)(1) 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.

**(i) Related Information**

(1) For more information about this AD, contact Tung Tran, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6505; fax: 425–917–6590; email: *tung.tran@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, WA 98124–2207; phone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this 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 17, 2015.

**Victor Wicklund,**

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

[FR Doc. 2015–10068 Filed 4–30–15; 8:45 am]

BILLING CODE 4910–13–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2008–0808; Directorate Identifier 2008–NE–18–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; General Electric Company CT58 Turboshaft Engines

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to supersede airworthiness directives (ADs) 2001–18–06 and 2008–22–16, which apply to certain General Electric Company (GE) CT58 turboshaft engines. ADs 2001–18–06 and 2008–22–16 require recalculating the lives of life-limited rotating parts using a Repetitive Heavy-Lift (RHL) multiplying factor and removal from service of parts that exceed the recalculated cyclic or hourly life limit. This proposed AD would consolidate ADs 2001–18–06 and 2008–22–16, and further reduce the life capability of certain parts. We are proposing this AD to prevent failure of life-limited rotating parts, uncontained part release, damage to the engine, and damage to the aircraft.

**DATES:** We must receive comments on this proposed AD by June 30, 2015.

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

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

For service information identified in this proposed AD, contact General Electric Company, GE Aviation, Room 285, One Neumann Way, Cincinnati, OH, 45215; phone: 513- 552–3272; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2008–0808; 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:** Sanjana Murthy, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7750; fax: 781–238–7199; email: *sanjana.murthy@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–2008–0808; Directorate Identifier 2008–NE–18–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 24, 2001, we issued AD 2001–18–06, Amendment 39–12432 (66 FR 47575, September 13, 2001), (''AD 2001–18–06''), and on October 20, 2008, we issued AD 2008–22–16, Amendment 39–15712 (73 FR 63629, October 27, 2008), (''AD 2008–22–16''), for CT58 turboshaft engines. AD 2001–18–06 requires the use of an RHL multiplying factor in calculating the lives of life-limited rotating parts used in RHL missions. AD 2008–22–16 addressed a shortfall in the life capability of compressor spools used in RHL operations. We issued ADs 2001–18–06 and 2008–22–16 to prevent cracks in rotating parts that could result in an uncontained engine failure, damage to the engine, and damage to the aircraft.

**Actions Since ADs 2001–18–06 and 2008–22–16 Were Issued**

Since we issued ADs 2001–18–06 and 2008–22–16, GE updated the life limits of compressor spools. GE also updated how to calculate the life consumption of compressor spools and of life-limited rotating parts flown in Utility operations. This update resulted in generally reduced lives for compressor spools and all other life-limited parts used in Utility operations. GE published their updated life calculations for all life-limited parts in GE Alert Service Bulletin (ASB) No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015.

**Relevant Service Information Under 1 CFR Part 51**

We reviewed GE ASB No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015. The service information describes procedures for calculating life limits for the affected life-limited rotating parts. This service information is reasonably available because the interested parties have access to it through their normal course of business or see **ADDRESSES** for other ways to access this service information.

**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 reduce the life limits of certain compressor spools used in all operations and, through imposition of a new lifing methodology, increase the life consumption of all rotating parts used in Utility operations.

**Costs of Compliance**

We estimate that this proposed AD would affect about 60 engines installed on aircraft of U.S. registry. The average pro-rated cost of the life-limited rotating parts is $20,000. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $8,715,000.

**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 to the extent that it justifies making a regulatory distinction, and

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

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

■ 2. The FAA amends § 39.13 by:

■ a. Removing airworthiness directives (AD) 2001–18–06; Amendment 39–12432 (66 FR 47575, September 13, 2001); and AD 2008–22–16, Amendment 39–15712 (73 FR 63629, October 27, 2008), and

■ b. Adding the following new AD:

**General Electric Company:** Docket No. FAA–2008–0808; Directorate Identifier 2008–NE–18–AD.

**(a) Comments Due Date**

The FAA must receive comments on this AD action by June 30, 2015.

**(b) Affected ADs**

This AD replaces AD 2001–18–06, Amendment 39–12432 (66 FR 47575, September 13, 2001) and AD 2008–22–16, Amendment 39–15712 (73 FR 63629, October 27, 2008.

**(c) Applicability**

This AD applies to all General Electric Company (GE) CT58–100–2, CT58–110–1, CT58–110–2, CT58–140–1, and CT58–140–2 turboshaft engines.

**(d) Unsafe Condition**

This AD was prompted by recalculation of life for parts installed on engines used in Utility operations, and a reduced life for compressor spools in all operations. We are issuing this AD to prevent failure of life-limited rotating parts, uncontained part release, damage to the engine, and damage to the aircraft.

**(e) Compliance**

Do the actions required by this AD, unless already done.

**(1) Calculating Cyclic Life Consumption**

Re-calculate the cycles-since-new for all compressor spools, and for life-limited rotating parts other than compressor spools used in Utility operations. Use paragraphs 3.A.(1) and 3.B.(1) in the Accomplishment Instructions of GE Alert Service Bulletin (ASB) No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015, to perform the calculations.

**(2) Removal of Compressor Spools**

After the effective date of this AD, remove compressor spools, part numbers (P/Ns) 5124T94G02, 6010T57G04, 6010T57G07, and 6010T57G08 from service, before reaching the life limits specified in paragraph 4.(1), Appendix A, in GE ASB No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015, as re-calculated per paragraph (e)(1) in this AD.

**(3) Removal of Rotating Parts Used in Utility Operations Other Than Compressor Spools**

After the effective date of this AD, remove from service any life-limited rotating part used in Utility operations other than the compressor spools with P/Ns listed in paragraph (e)(2) of this AD that exceeds its life limit, as re-calculated per paragraph (e)(1) in this AD. Use Tables I, II, III, and IV in paragraphs 3.D. through 3.G. in the Accomplishment Instructions in GE ASB No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015, and paragraph 4.(4), Appendix A, of this GE ASB, to determine when to remove these parts.

**(4) Removal of Rotating Parts Not Used in Utility Operations Other Than Compressor Spools**

After the effective date of this AD, remove from service any life-limited rotating part not used in Utility operations other than the compressor spools with P/Ns listed in paragraph (e)(2) of this AD that exceeds its life limits. Use Tables I, II, III, and IV in paragraphs 3.D. through 3.G. in the Accomplishment Instructions in GE ASB No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015, and paragraph 4.(3), Appendix A of this GE ASB to determine when to remove these parts.

**(f) Alternative Methods of Compliance (AMOCs)**

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

**(g) Related Information**

(1) For more information about this AD, contact Sanjana Murthy, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7750; fax: 781–238–7199; email: *sanjana.murthy@faa.gov.*

(2) GE ASB No. CT58 S/B 72–A0162, Revision 16, dated January 7, 2015, can be obtained from GE using the contact information in paragraph (g)(3) of this proposed AD.

(3) For service information identified in this AD, contact General Electric Company, GE Aviation, Room 285, One Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.*

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

Issued in Burlington, Massachusetts, on April 17, 2015.

**Thomas A. Boudreau,**

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

[FR Doc. 2015–09932 Filed 4–30–15; 8:45 am]

BILLING CODE 4910–13–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2015–1177; Directorate Identifier 2015–CE–009–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Pilatus Aircraft LTD. Airplanes

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for Pilatus Aircraft Ltd. Model PC–12/47 and PC–12/47E airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as the aileron trim tab disconnecting above 10,000 feet altitude. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

**DATES:** We must receive comments on this proposed AD by June 15, 2015.

**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 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Pilatus Aircraft Ltd, Customer Support Manager, CH–6371 STANS, Switzerland; phone: +41 (0)41 619 33 33; fax: +41 (0)41 619 73 11; email: *SupportPC12@pilatus-aircraft.com;* Internet: *http://www.pilatus-aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

### Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1177; 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 (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–1177; Directorate Identifier 2015–CE–009–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://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

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No.: 2015–0060, dated April 10, 2015 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

During a continued airworthiness review, a potential unsafe condition was identified that could result from a disconnected aileron trim tab occurring above an altitude of 10.000 feet.

This condition, if not corrected, could lead, in case of a disconnection of an aileron trim tab, to undamped aeroplane vibrations, potentially resulting in structural failure.

To address this potential unsafe condition, Pilatus Aircraft Ltd. issued SB No. 27–021 to provide instructions for replacement of the aileron tab counter balance weight.

For the reason described above, this AD requires replacement of the aileron tab counter balance weight with a new, slightly heavier, aileron tab counter balance weight.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1177.

## Related Service Information Under 1 CFR Part 51

Pilatus Aircraft Ltd. has issued PILATUS PC–12 Service Bulletin No: 27–021, dated January 20, 2015. The PILATUS PC–12 Service Bulletin No: 27–021, dated January 20, 2015, describes procedures to replace the aileron tab counter balance weight. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

## FAA's Determination and Requirements of the 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 this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

## Costs of Compliance

We estimate that this proposed AD will affect 303 products of U.S. registry. We also estimate that it would take about 5.5 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $1,000 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $444,652.50, or $1,467.50 per product.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

## 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.

## 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 AD:

**Pilatus Aircraft Ltd.:** Docket No. FAA–2015–1177; Directorate Identifier 2015–CE–009–AD.

**(a) Comments Due Date**

We must receive comments by June 15, 2015.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to the following Pilatus Aircraft Ltd. model and serial number airplanes, certificated in any category.

(1) Model PC–12/47, manufacturer serial numbers (MSNs) 684 through MSN 888; and

(2) Model PC–12/47E, MSNs 545, and 1001 through 1520.

**(d) Subject**

Air Transport Association of America (ATA) Code 27: Flight Controls.

**(e) Reason**

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as the aileron trim tab disconnecting above 10,000 feet altitude. We are issuing this AD to prevent a disconnected aileron trim tab, which could lead to undamped airplane vibrations, potentially resulting in structural failure.

**(f) Actions and Compliance**

Unless already done, do the following actions:

(1) For airplanes equipped with aileron trim tab assembly, part number (P/N) 527.15.12.037 or 527.15.12.038; or aileron assembly, P/N 557.05.12.015, 557.05.12.016, 557.05.12.017, or 557.05.12.018, within 12 months after the effective date of this AD, replace the aileron tab counter balance weight and re-identify the aileron trim tab assembly following the instructions of Pilatus PC–12 Service Bulletin No: 27–021, dated January 20, 2015.

(2) For an airplane that on the effective date of this AD has an aileron trim tab assembly, P/N 27.15.12.037 or 527.15.12.038, installed: After modification of that airplane as required by paragraph (f)(1) of this AD, do not install another aileron trim tab assembly with P/N 527.15.12.037 or 527.15.12.038.

(3) For an airplane that on the effective date of this AD does not have an aileron trim tab assembly, P/N 27.15.12.037 or 527.15.12.038, installed: After the effective date of this AD, do not install an aileron trim tab assembly with P/N 527.15.12.037 or 527.15.12.038.

(4) After the effective date of this AD, you are allowed to install on an airplane an aileron assembly, having a P/N 557.05.12.015, 557.05.12.016, 557.05.12.017, or 557.05.12.018, provided that an aileron trim tab assembly, P/N 527.15.12.037 or 527.15.12.038 is not installed on the airplane.

**(g) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(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.

**(h) Related Information**

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2015–0060, dated April 10, 2015, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1177. For service information related to this AD, contact PILATUS AIRCRAFT LTD, Customer Support Manager, CH–6371 STANS, Switzerland; phone: +41 (0)41 619 33 33; fax: +41 (0)41 619 73 11; email: *SupportPC12@pilatus-aircraft.com;* Internet: *http://www.pilatus-aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on April 23, 2015.

**Earl Lawrence,**

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

[FR Doc. 2015–10073 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2015–0277; Directorate Identifier 2015–NE–05–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; CFM International S.A. Turbofan Engines

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain CFM International S.A. (CFM) CFM56–7B series turbofan engines. This proposed AD was prompted by reports of uncommanded in-flight shutdowns (IFSDs) on CFM CFM56–7B engines following rupture of the 73-tooth gearshaft located in the engine accessory gearbox (AGB). This proposed AD would require magnetic chip detector (MCD) inspection of the affected gearshafts until removal. We are proposing this AD to prevent failure of certain engine AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

**DATES:** We must receive comments on this proposed AD by June 30, 2015.

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

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

For service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

*Examining the AD Docket*

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0277; 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:** Kyle Gustafson, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7183; fax: 781–238–7199; email: *kyle.gustafson@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–0277; Directorate Identifier 2015–NE–05–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

We have received reports of uncommanded IFSDs on CFM CFM56–7B engines following rupture of the 73-tooth gearshaft located in the engine AGB. CFM has identified an affected population of 73-tooth gearshafts that show premature wear on the teeth due to inadequate shot peening. In the process of its investigation, CFM identified an additional population of 41-tooth gearshafts that is subject to the same premature wear. The affected population of 73-tooth and 41-tooth gearshafts exhibit a surface finish that leads to loss in oil film effectiveness, causing micro-pitting which eventually

leads to material separating from the gearshaft and its eventual failure.

The proposed AD requires enhanced MCD inspection until removal of the gearshaft. This enhanced inspection requires that any material, including fuzz, be sent to the particles lab for analysis to determine the source of the material. We are allowing affected engines to continue to operate for 75 flight hours (FHs) after the MCD inspection to provide sufficient time to determine the source of the material and to remove the affected gearshaft if the particles lab analysis finds that the source of the material is from an affected 73-tooth or 41-tooth gearshaft. The enhanced MCD inspection and particles lab analysis is repeated every 500 FHs after the initial MCD inspection until the affected gearshaft is removed from service. This condition, if not corrected, could result in failure of certain engine AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

**Relevant Service Information Under 1 CFR Part 51**

We reviewed CFM Service Bulletin (SBs) CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014, and CFM56–7B S/B 72–0965, dated December 16, 2014. The SBs describe procedures for removal of affected 73-tooth and 41-tooth gearshafts. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

**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 require an MCD inspection within 250 FHs since last inspection or within 25 FHs after the effective date of this AD, whichever comes later. The proposed AD would also require that the MCD inspection be repeated every 500 FHs after the initial MCD inspection until removal of the affected gearshaft. The proposed AD would also require as terminating action that the affected gearshafts be removed.

**Differences Between This Proposed AD and the Service Information**

This proposed AD would require an MCD inspection 250 FHs since last inspection or within 25 FHs after the effective date of this AD, whichever comes later. CFM SB CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014, recommends performing a MCD inspection 250 FHs since last inspection or as soon as possible if the inspection was done more than 250 FHs ago.

In this proposed AD, we are not requiring that operators send the particles to CFM for analysis. We are, however, requiring that operators determine if the particles are 73-tooth gearshaft or 41-tooth gearshaft material. CFM56–7B S/B 72–0964 recommends that if any magnetic particles, including fuzz are seen, operators send the inspection results and lab analysis to CFM for disposition.

**Costs of Compliance**

We estimate that this proposed AD would affect about 67 engines installed on airplanes of U.S. registry. We also estimate that it would take about 1 hour per engine to do the inspection and 8 hours per engine to replace each affected gearshaft. We estimate thirty-six 73-tooth gearshafts and forty 41-tooth gearshafts will need replacement at a cost of $12,480 and $7,680 per part, respectively. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $813,855.

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

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

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

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

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

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

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

**CFM International S.A.:** Docket No. FAA–2015–0277; Directorate Identifier 2015–NE–05–AD.

**(a) Comments Due Date**

We must receive comments by June 30, 2015.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to CFM International S.A. (CFM) CFM56–7B engines with accessory gearboxes (AGBs), with 73-tooth gearshafts or 41-tooth gearshafts, identified in Appendix A and Appendix B of CFM Service Bulletin (SB) CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014.

**(d) Unsafe Condition**

This AD was prompted by reports of uncommanded in-flight shutdowns on CFM CFM56–7B engines following rupture of the 73-tooth gearshaft located in the engine AGB. We are issuing this AD to prevent failure of certain AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

**(e) Compliance**

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

(1) *Initial Magnetic Chip Detector (MCD) Inspection and Analysis.* (i) For affected 73-tooth gearshafts, perform an MCD inspection within 250 flight hours (FHs) since last inspection, within 25 FHs from the effective date of this AD, or when the gearshaft accumulates 3,000 FHs since new, whichever comes later.

(ii) For affected 41-tooth gearshafts, perform an MCD inspection within 250 FHs since last inspection, within 25 FHs from the effective date of this AD, or when the gearshaft accumulates 6,000 FHs since new, whichever comes later.

(iii) If any magnetic particles, including fuzz, are seen, determine with particles lab analysis if the particles are 73-tooth or 41-tooth gearshaft material.

(iv) If the particles are 73-tooth or 41-tooth gearshaft material, remove the affected gearshaft(s) within 75 FHs since the MCD inspection.

(2) *Repetitive MCD Inspection and Analysis.* (i) For affected 73-tooth gearshafts, perform an MCD inspection and particles lab analysis within every 500 FHs since the last MCD inspection until affected gearshaft is removed.

(ii) For affected 41-tooth gearshafts, perform an MCD inspection and particles lab analysis within every 500 FHs since the last MCD inspection until affected gearshaft is removed.

(iii) If any magnetic particles, including fuzz, are seen, determine with particles lab analysis if the particles are 73-tooth or 41-tooth gearshaft material.

(iv) If the particles are 73-tooth or 41-tooth gearshaft material, remove the affected gearshaft(s) within 75 FHs since the MCD inspection.

**(f) Mandatory Terminating Action**

(1) Remove the affected 73-tooth gearshaft prior to the gearshaft accumulating 6,000 FHs since new or within 50 FHs after the effective date of this AD, whichever comes later.

(2) Remove the affected 41-tooth gearshaft prior to the gearshaft accumulating 9,000 FHs since new or within 50 FHs after the effective date of this AD, whichever comes later.

**(g) Installation Prohibition**

After the effective date of this AD, do not install an affected gearshaft into an AGB.

**(h) Alternative Methods of Compliance (AMOCs)**

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

**(i) Related Information**

(1) For more information about this AD, contact Kyle Gustafson, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7183; fax: 781–238–7199; email: *kyle.gustafson@faa.gov.*

(2) CFM SBs CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014, and CFM56–7B S/B 72–0965, dated December 16, 2014, can be obtained from GE using the contact information in paragraph (i)(3) of this proposed AD.

(3) For service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.*

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

Issued in Burlington, Massachusetts, on April 17, 2015.

**Thomas A. Boudreau,**

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

[FR Doc. 2015–09930 Filed 4–30–15; 8:45 am]

BILLING CODE 4910–13–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2014–1069; Airspace Docket No. 14–ANM–11]**

## Proposed Amendment of Class D and Class E Airspace, Revocation of Class E Airspace; Salem, OR

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to modify Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface, and remove Class E surface area airspace designated as an extension at McNary Field, Salem, OR. After a biennial review, the FAA found it necessary to amend the airspace area for the safety and management of Instrument Flight Rules (IFR) operations for Standard Instrument Approach Procedures (SIAPs) at the airport.

**DATES:** Comments must be received on or before June 15, 2015.

**ADDRESSES:** Send comments on this proposal 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; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2014–1069; Airspace Docket No. 14–ANM–11, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this proposed incorporation by reference material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783.

**FOR FURTHER INFORMATION CONTACT:** Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4563.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2014–1069/Airspace Docket No. 14–ANM–11.'' The postcard will be date/time stamped and returned to the commenter.

**Availability of NPRMs**

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

**Availability and Summary of Documents Proposed for Incorporation by Reference**

This document proposes to amend FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**The Proposal**

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class D surface area airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface, and removing Class E surface area airspace as an extension at McNary Field, Salem, OR. After a biennial review of the airspace, the FAA found modification of the airspace necessary for the safety and management of IFR operations for SIAPs at the airport. Class D airspace and Class E surface area airspace would extend upward from the surface to and including 2,700 feet within a 4-mile radius northeast of McNary Field, extending to 6.2 miles to the southeast, and 8.1 miles from the southeast to the northwest, excluding that airspace within 1.2 NM of Independence State Airport, OR. Class E airspace extending upward from 700 feet above the surface would be modified to within a 6.5-mile radius northeast of McNary Field, extending to 8.2 miles to the southeast, and 9.1 miles from the southeast to the northwest, excluding that airspace within 1.2 NM of Independence State Airport, OR.

Class D and Class E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order 7400.9Y, dated August 6, 2014 and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace at McNary Field, Salem, OR.

**Environmental Review**

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

*Paragraph 5000: Class D airspace.*

* * * * *

**ANM OR D Salem, OR [Modified]**

Salem, McNary Field, OR
(Lat. 44°54′34″ N., long. 123°00′09″ W.)
Independence, Independence State Airport, OR
(Lat. 44°52′01″ N., long. 123°11′54″ W.)

That airspace extending upward from the surface to and including 2,700 feet MSL within a 4-mile radius of McNary Field from the 330° bearing from the airport clockwise to the 074° bearing, and that airspace within a 6.2-mile radius of McNary Field from the 074° bearing from the airport clockwise to the 150° bearing, and that airspace within a 8.1-mile radius of McNary Field from the 150° bearing from the airport clockwise to the 330° bearing, excluding that airspace within 1.2 NM of Independence State Airport, OR. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

*Paragraph 6002: Class E Airspace Designated as Surface Areas.*

* * * * *

**ANM OR E2 Salem, OR [Modified]**

Salem, McNary Field, OR
(Lat. 44°54′34″ N., long. 123°00′09″ W.)
Independence, Independence State Airport, OR
(Lat. 44°52′01″ N., long. 123°11′54″ W.)

That airspace extending upward from the surface to and including 2,700 feet MSL within a 4-mile radius of McNary Field from the 330° bearing from the airport clockwise

to the 074° bearing, and that airspace within a 6.2-mile radius of McNary Field from the 074° bearing from the airport clockwise to the 150° bearing, and that airspace within a 8.1-mile radius of McNary Field from the 150° bearing from the airport clockwise to the 330° bearing, excluding that airspace within 1.2 NM of Independence State Airport, OR. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

*Paragraph 6004: Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.*

* * * * *

**ANM OR E4 Salem, OR [Removed]**

*Paragraph 6005: Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

**ANM OR E5 Salem, OR [Modified]**

Salem, McNary Field, OR
(Lat. 44°54′34″ N., long. 123°00′09″ W.)
Independence, Independence State, OR
(Lat. 44°52′01″ N., long. 123°11′54″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of McNary Field from the 330° bearing from the airport clockwise to the 074° bearing, and that airspace within a 8.2-mile radius of McNary Field from the 074° bearing from the airport clockwise to the 150° bearing, and that airspace within a 9.1-mile radius of McNary Field from the 150° bearing from the airport clockwise to the 330° bearing, excluding that airspace within 1.2 NM of Independence State Airport, OR.

Issued in Seattle, Washington, on April 21, 2015.

**Christopher Ramirez,**

*Acting Manager, Operations Support Group, Western Service Center, AJV–W2.*

[FR Doc. 2015–10048 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2015–0691; Airspace Docket No. 15–ANM–6]**

## Proposed Establishment of Class E Airspace and Modification of Class D Airspace; Ogden, Hill AFB, UT

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to establish Class E airspace and modify Class D airspace at Hill Air Force Base (AFB), Ogden, UT. This action, initiated by the FAA's biennial review of the airspace area, would enhance the safety and management of Instrument Flight Rules (IFR) operations for Standard Instrument Approach Procedures (SIAPs) at the airport. This action would also update the geographic coordinates for Hill AFB, and Ogden-Hinckley Airport.

**DATES:** Comments must be received on or before June 15, 2015.

**ADDRESSES:** Send comments on this proposal 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; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2015–0691; Airspace Docket No. 15–ANM–6, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this proposed incorporation by reference material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783.

**FOR FURTHER INFORMATION CONTACT:** Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4517.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–0691/Airspace Docket No. 15–ANM–6.'' The postcard will be date/time stamped and returned to the commenter.

### Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

### Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**The Proposal**

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace as an extension to Class D surface area, modifying Class D airspace at Hill AFB, Ogden, UT. Class E airspace as an extension to the Class D would be established with a segment extending 1 mile southeast of the airport. The Class D airspace area boundary between Hill AFB and Ogden-Hinckley Airport would be moved 1 mile northwest and the radius of Hill AFB expanded from 4.3 miles to 4.6 miles. This action would also update the geographic coordinates for Hill AFB and Ogden-Hinckley Airport. After a review of the airspace, the FAA found modification of the airspace necessary for the safety and management of aircraft departing and arriving under IFR operations at the airport.

Class D and Class E airspace designations are published in paragraph 5000 and 6004, respectively, of FAA Order 7400.9Y, dated August 6, 2014 and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace at Hill AFB, Ogden UT.

**Environmental Review**

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

*Paragraph 5000 Class D airspace.*

* * * * *

**ANM UT D Ogden, Hill AFB, UT [Modified]**

Hill AFB, UT
(Lat. 41°07′26″ N., long. 111°58′23″ W.)
Ogden-Hinckley Airport, UT
(lat. 41°11′44″ N., long. 112°00′47″ W.)

That airspace extending upward from the surface up to, but not including, 7,800 feet within a 4.6-mile radius of Hill AFB, excluding that airspace north of a line beginning at a point where the Ogden-Hinckley Airport 216° radial intersects the Hill AFB 4.6-mile radius, thence counter clockwise along the 4.6-mile radius to the point where the Ogden-Hinckley Airport 99° radial intersects the Hill AFB–4.6 mile radius, thence northwest to lat. 41°10′56″ N., long. 111°59′19″ W.; to lat. 41°10′21″ N, long. 112°00′55″ W., to the point of beginning. This airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published in the Airport/Facility Directory.

*Paragraph 6004 Class E airspace areas designated as an extension to Class D or Class E surface area.*

* * * * *

**ANM UT E4 Ogden, Hill AFB, UT [New]**

Hill AFB, UT
(Lat. 41°07′26″ N., long. 111°58′23″ W.)
Hill AFB, point in space coordinates
(Lat. 41°06′27″ N., long.111°57′43″ W.)

That airspace extending upward from the surface within a 4.5-mile radius of point in space coordinates at lat. 41°06′27″ N., long. 111°57′43″ W.

Issued in Seattle, Washington, on April 21, 2015.

**Christopher Ramirez,**

*Manager (Acting), Operations Support Group, Western Service Center.*

[FR Doc. 2015–10050 Filed 4–30–15; 8:45 am]

BILLING CODE 4901–13–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2015–0671; Airspace Docket No. 15–ANM–5]**

## Proposed Establishment of Class E Airspace, and Amendment of Class D and E Airspace; Ogden-Hinckley Airport, UT

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

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to establish Class E airspace as an extension to the Class D surface area, modify Class D airspace, and Class E airspace extending from 700 feet above the surface at Ogden-Hinckley Airport, Ogden, UT. This action, initiated by the FAA's biennial review of the airspace area, would enhance the safety and management of Instrument Flight Rules (IFR) operations for Standard Instrument Approach Procedures (SIAPs) at the airport. This action would also update the geographic coordinates of Ogden-Hinckley Airport and Hill AFB, Ogden, UT.

**DATES:** Comments must be received on or before June 15, 2015.

**ADDRESSES:** Send comments on this proposal 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; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2015–0671; Airspace Docket No. 15–ANM–5, at the beginning of your comments. You may also submit

comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this proposed incorporation by reference material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC, 20591; telephone: 202–267–8783.

**FOR FURTHER INFORMATION CONTACT:** Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4517.

**SUPPLEMENTARY INFORMATION:**

## Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–0671/Airspace Docket No. 15–ANM–5.'' The postcard will be date/time stamped and returned to the commenter.

## Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

## Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

## The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace as an extension to the Class D surface area, modifying Class D airspace, and Class E airspace extending upward from 700 feet above the surface at Ogden-Hinckley Airport, Ogden, UT. Class E airspace as an extension to the Class D surface area would be established with a segment extending from the 4.3-mile radius of the airport to 16 miles southwest of the airport. The Class D airspace common boundary between Ogden-Hinckley Airport and Hill AFB, Ogden, UT, would be moved 1 mile northwest. Class E airspace extending upward from 700 feet above the surface would be modified to within a 5.3-mile radius of the airport, with segments extending from the 5.3-mile radius to 11 miles northwest, and 13 miles southwest of the airport. This action would also update the geographic coordinates for Ogden-Hinckley Airport and Hill AFB. After a review of the airspace, the FAA found this action necessary for the safety and management of aircraft departing and arriving under IFR operations at the airport.

Class D and Class E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.9Y, dated August 6, 2014 and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace at Ogden-Hinckley Airport, Ogden UT.

## Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E,

''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014 and effective September 15, 2014, is amended as follows:

*Paragraph 5000 Class D airspace.*

* * * * *

**ANM UT D Ogden-Hinckley Airport, UT [Modified]**

Ogden-Hinckley Airport, UT
(Lat. 41°11′44″ N., long. 112°00′47″ W.)
Hill AFB, UT
(Lat. 41°07′26″ N., long. 111°58′23″ W.)

That airspace extending upward from the surface up to, but not including, 7,800 feet within a 4.3-mile radius of the Ogden-Hinckley Airport, and that airspace beginning at a point where the Ogden-Hinckley 216° radial intersects the Hill AFB 4.6-mile radius to the point where the Ogden-Hinckley 231° radial intersects the 4.3-mile radius, thence clockwise along the 4.3-mile radius to where the Ogden-Hinckley 84° radial intersects the 4.3-mile radius to the point where the Ogden-Hinckley 99° radial intersects the Hill AFB 4.6-mile radius, excluding the portion southeast of a line beginning where the 216° radial intersects the Hill AFB 4.6-mile radius, thence northeast to lat. 41°10′21″ N., long. 112°00′55 W.; to lat. 41°10′56″ N., long. 111°59′19″ W.; to a point where the Ogden-Hinckley 99° radial intersects the Hill AFB 4.6-nm radius. This airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published in the Airport/Facility Directory.

*Paragraph 6004 Class E airspace areas designated as an extension to Class D or Class E surface area.*

* * * * *

**ANM UT E4 Ogden-Hinckley Airport, UT [New]**

Ogden-Hinckley Airport, UT
(Lat. 41°11′44″ N., long. 112°00′47″ W.)
Hill AFB, UT
(Lat. 41°07′26″ N., long. 111°58′23″ W.)

That airspace extending upward from the surface 4 miles north and parallel to the 225° radial of the Ogden-Hinckley Airport, extending from the 4.3-mile radius to 16 miles southwest of the airport, thence southeast to lat.41°2′40″ N., long.112°20′4″ W., thence northeast to the point where the Ogden-Hinckley 99° radial intersects the Hill AFB 4.6-nm radius.

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

**ANM UT E5 Ogden-Hinckley Airport, UT [Modified]**

Ogden-Hinckley Airport, UT
(Lat. 41°11′44″ N., long. 112°00′47″ W.)

That airspace extending upward from 700 feet above the surface within a 5.3-mile radius of Ogden-Hinckley Airport, and that airspace 3 miles either side of the 294° radial from the airport extending from the 5.3-mile radius to 11 miles northwest of the airport, and that airspace 4 miles either side of the Ogden-Hinckley 226° radial from the 5.3-mile radius to 13 miles southwest of the airport.

Issued in Seattle, Washington, on April 21, 2015.

**Christopher Ramirez,**

*Acting Manager, Operations Support Group, Western Service Center.*

[FR Doc. 2015–10044 Filed 4–30–15; 8:45 am]

BILLING CODE 4901–13P

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 147

**[Docket No. USCG–2015–0247]**

**RIN 1625–AA00**

## Safety Zone; POLAR PIONEER, Outer Continental Shelf Drill Unit, Chukchi Sea, Alaska

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes a safety zone that extends 500 meters from the outer edge of the DRILL UNIT POLAR PIONEER, as well as 500 meters from those points, suitably marked by a buoy, where the DRILL UNIT POLAR PIONEER's mooring spread meets the ocean's surface. This safety zone would be in effect both when the DRILL UNIT POLAR PIONEER is anchored and when deploying and recovering moorings. Placing a safety zone around the drilling unit will significantly reduce the threat of allisions, which could result in oil spills and releases of natural gas, and thereby protects the safety of life, property, and the environment. Lawful demonstrations may be conducted outside of the safety zone.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 1, 2015.

**ADDRESSES:** You may submit comments identified by docket number USCG–2015–0247 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* 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.

(4) *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.

To avoid duplication, please use only one of these four 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 proposed rule, call or email LCDR Jason Boyle, Seventeenth Coast Guard District (dpi); telephone 907–463–2821, *Jason.t.boyle@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

### A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

*1. Submitting Comments*

If you submit a comment, please include the docket number for this rulemaking (USCG–2015–0247), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *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 via *http://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 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–2015–0247 in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

*2. Viewing Comments and Documents*

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number USCG–2015–0247 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.

*3. 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).

*4. Public Meeting*

The Coast Guard does not plan to hold a public meeting. But you may submit a request for one by using one of the four 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**.

**B. Basis and Purpose**

The Coast Guard proposes the establishment of a temporary safety zone around the DRILL UNIT POLAR PIONEER while anchored or deploying and recovering moorings on location in order to drill exploratory wells in several prospects located in the Chukchi Sea during the 2015 drilling season. The purpose of the temporary safety zone is to protect the drilling unit from vessels operating outside the normal shipping channels and fairways.

The request for the temporary safety zone was made by Shell Exploration & Production Company due to safety concerns for both the personnel aboard the DRILL UNIT POLAR PIONEER and the environment. Shell Exploration & Production Company indicated that it is highly likely that any allision or inability to identify, monitor or mitigate any risks or threats, including ice-related hazards that might be encountered, may result in a catastrophic event. Incursions into the safety zone by unapproved vessels could degrade the ability to monitor and mitigate such risks. In evaluating this request, the Coast Guard explored relevant safety factors and considered several criteria, including but not limited to: (1) The level of shipping activity around the operation; (2) safety concerns for personnel aboard the vessel; (3) concerns for the environment given the sensitivity of the environmental and the importance of fishing and hunting to the indigenous population; (4) the lack of any established shipping fairways, and fueling and supply storage/operations which increase the likelihood that an allision would result in a catastrophic event; (5) the recent and potential future maritime traffic in the vicinity of the proposed areas; (6) the types of vessels navigating in the vicinity of the proposed area; (7) the structural configuration of the vessel, and (8) the need to allow for lawful demonstrations without endangering the safe operation of the vessel.

Results from a thorough and comprehensive examination of the criteria, IMO guidelines, and existing regulations warrant the establishment of the proposed temporary safety zone. A safety zone would significantly reduce the threat of allisions that could result in oil spills, and other releases. Furthermore, a safety zone would increase the safety of life, property, and the environment in the Chukchi Sea by prohibiting entry into the zone unless specifically authorized by the Commander, Seventeenth Coast Guard District, or a designated representative. Due to the remote location and the need to protect the environment, the Coast Guard may use criminal sanctions to enforce the safety zone as appropriate.

Shell Exploration & Production Company has proposed and received permits for drill sites within the Burger prospects, Chukchi Sea, Alaska.

Based on the anticipated drilling operations, we believe a safety zone is needed be around the DRILL UNIT POLAR PIONEER while anchored or deploying and recovering moorings on location in order to drill exploratory wells in various locations in the Chukchi Sea Outer Continental Shelf, Alaska during the 2015 timeframe.

The actual order of drilling activities will be controlled by an interplay between actual ice conditions immediately prior to a rig move, ice forecasts, any regulatory restrictions with respect to the dates of allowed operating windows, whether the planned drilling activity involves only drilling the shallow non-objective section or penetrating potential hydrocarbon zones, the availability of permitted sites having approved shallow hazards clearance, the anticipated duration of each contemplated drilling activity, the results of preceding wells and Marine Mammal Monitoring and Mitigation plan requirements.

All planned exploration drilling in the identified lease will be conducted with the DRILL UNIT POLAR PIONEER. While conducting exploration drilling operations, the DRILL UNIT POLAR PIONEER will be anchored using an anchoring system consisting of an 8-point anchored mooring spread attached to the onboard turret and could have a maximum anchor radius of 3,600 ft (1,100 m). The center point of the DRILL UNIT POLAR PIONEER will be positioned within the prospect location in the Chukchi Sea.

The DRILL UNIT POLAR PIONEER will move into the Chukchi Sea on or about July 1, 2015 and onto a prospect location when ice allows. Drilling will conclude on or before October 31, 2015. The drillship and support vessels will depart the Chukchi Sea at the conclusion of the 2015 drilling season.

**C. Discussion of Proposed Rule**

The proposed temporary safety zone would encompass the area that extends 500 meters from the outer edge of the DRILL UNIT POLAR PIONEER, as well as 500 meters from those points, suitably marked by a buoy, where the DRILL UNIT POLAR PIONEER's mooring spread meets the ocean's surface. As a result, the size and shape of the safety zone would vary, depending on how far from the vessel the mooring spread is deployed, which is expected to be no more than 1,000 meters. This safety zone would be in effect when the DRILL UNIT POLAR PIONEER is on location in order to drill exploratory wells at various prospects located in the Chukchi Sea Outer Continental Shelf, Alaska, from 12:01 a.m. on July 1, 2015 through 11:59 p.m. on October 31, 2015.

This safety zone will be in effect both when the DRILL UNIT POLAR PIONEER is anchored and when deploying and recovering moorings. As a result, the size and shape of the safety zone will vary, depending on how far from the vessel the mooring spread is deployed, which is expected to be no more than 1,000 meters. No vessel would be allowed to enter or remain in this proposed safety zone except the following: An attending vessel or a vessel authorized by the Commander, Seventeenth Coast Guard District or a designated representative. They may be contacted on VHF–FM Channel 13 or 16 or by telephone at 907–463–2000. For any group intending to conduct lawful demonstrations in the vicinity of the rig, these demonstrations must be conducted outside the safety zone.

**D. Regulatory Analyses**

The Coast Guard developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

*1. Regulatory Planning and Review*

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

We expect the economic impact of this rule will not rise to the level of necessitating a full Regulatory Evaluation. This rule is not a significant regulatory action due to the location of the DRILL UNIT POLAR PIONEER on the Outer Continental Shelf and its distance from both land and safety fairways. Vessels traversing waters near the proposed safety zone will be able to safely travel around the zone without incurring additional costs.

*2. Small Entities*

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612), the Coast Guard has considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the Burger Prospects of the Chukchi Sea.

This safety zone will not have a significant economic impact or a substantial number of small entities for the following reasons: This rule will enforce a safety zone around a drilling unit facility that is in areas of the Chukchi Sea not frequented by vessel traffic and is not in close proximity to a safety fairway. Further, vessel traffic can pass safely around the safety zone without incurring additional costs.

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

*3. Assistance for Small Entities*

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact LCDR Jason Boyle, Coast Guard Seventeenth District, Office of Prevention; telephone 907–463–2821, *Jason.t.boyle@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

*4. Collection of Information*

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

*5. Federalism*

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

*6. Protest Activities*

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

*7. Unfunded Mandates Reform Act*

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000.00 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

*8. Taking of Private Property*

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

*9. Civil Justice Reform*

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

*10. Protection of Children*

The Coast Guard has analyzed this proposed rule under Executive Order

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

*11. Indian Tribal Governments*

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

*12. Energy Effects*

The Coast Guard analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

*13. Technical Standards*

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

*14. Environment*

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

**List of Subjects in 33 CFR Part 147**

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 147 as follows:

## PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

**Authority:** 14 U.S.C. 85; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.T17–0247 to read as follows:

**§ 147.T17–0247 Safety Zone; DRILL UNIT POLAR PIONEER, Outer Continental Shelf Drillship, Chukchi Sea, Alaska.**

(a) *Description.* The DRILL UNIT POLAR PIONEER will be engaged in exploratory drilling operations at various locations in the Chukchi Sea from July 1, 2015 through October 31, 2015. The DRILL UNIT POLAR PIONEER will be anchored while conducting exploratory drilling operations with the center point of the vessel located in various locations in the Chukchi Sea. The area that extends 500 meters from the outer edge of the DRILL UNIT POLAR PIONEER, as well as 500 meters from those points, suitably marked by a buoy, where the DRILL UNIT POLAR PIONEER's mooring spread meets the ocean's surface is a safety zone. Lawful demonstrations may be conducted outside of the safety zone.

(b) *Regulation.* No vessel may enter or remain in this safety zone except the following:

(1) An attending vessel; or

(2) A vessel authorized by the Commander, Seventeenth Coast Guard District, or a designated representative.

Dated: April 8, 2015.

**Daniel B. Abel,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.*

[FR Doc. 2015–10259 Filed 4–30–15; 8:45 am]

BILLING CODE 9110–04–P

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket Number USCG–2015–0246]**

**RIN 1625–AA00**

## Safety Zone—Oil Exploration Staging Area in Dutch Harbor, AK

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes temporary safety zones in the Port of Dutch Harbor, Broad Bay, and adjacent navigable waters in the Dutch Harbor area on June 15, 2015. The temporary safety zones would encompass the navigable waters within a 25-yard radius of moored or anchored offshore exploration or support vessels, and the navigable waters within a 100-yard radius of underway offshore exploration or support vessels. The purpose of the safety zones is to protect persons and vessels during an unusually high volume of vessel traffic in the Port of Dutch Harbor, and the adjacent territorial sea due to additional vessel traffic associated with exploratory drilling operations in the Chukchi and Beaufort seas during the summer of 2015. Lawful demonstrations are permitted outside of the temporary safety zones so long as they do not endanger the safety of vessels either moored or anchored within the port, transiting through the port, or transiting through the adjacent waters of the territorial sea.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 1, 2015.

**ADDRESSES:** You may submit comments identified by docket number USCG–2015–0246 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, 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.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email LT Heikki Laukkanen, Sector Anchorage Prevention, Coast Guard; telephone 907–428–4186, email *Heikki.J.Laukkanen@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

**Table of Acronyms**

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

**A. Public Participation and Request for Comments**

We encourage you to participate in this rulemaking by submitting

comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

*1. Submitting Comments*

If you submit a comment, please include the docket number for this rulemaking, (USCG–2015–0246), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online 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 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 Docket Management Facility. We recommend 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–2015–0246] in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

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*2. Viewing Comments and Documents*

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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).

*4. Public Meeting*

The Coast Guard does not now plan to hold a public meeting 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 one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

**B. Regulatory History and Information**

Similar safety zones were implemented in previous years when oil exploration equipment was staged in Dutch Harbor, most recently in 2012.

**C. Basis and Purpose**

It is anticipated that vessels associated with exploratory drilling operations will call upon the Port of Dutch Harbor en route to proposed drilling sites in the Chukchi and Beaufort Seas. Based on information provided by private entities affiliated with oil exploration activities, the Coast Guard anticipates approximately 28 exploration or support vessels will call on Dutch Harbor during the period of time that the temporary safety zones are in effect. The addition of these vessels in conjunction with the high volume of traffic operating within the Port of Dutch Harbor creates a safety risk for all vessels operating therein. Such risks include reduced ability to navigate safely within the congested waterways of the port during the subject time period. To address these risks, the Coast Guard is proposing safety zones to ensure safe and efficient vessel transits within the Port of Dutch Harbor and the adjacent territorial sea. The increased maritime traffic through the Port of Dutch Harbor and the adjacent territorial sea can potentially create a scenario where the safety of vessels transiting through this area is placed at heightened risk.

Based on the expectation of increased maritime traffic, the Coast Guard believes temporary safety zones are needed to address safety concerns for personnel aboard the support vessels, mariners operating other vessels in the vicinity of Dutch Harbor, and to protect the environment. The vessels and equipment anticipated to be staged within these areas, due to their size and technical complexity, pose a safety risk to vessels that attempt to navigate too closely to them. Limited rescue capabilities are available in the area. In an effort to mitigate the safety risks and any resulting environmental damage, the Coast Guard is proposing temporary safety zones within the Port of Dutch Harbor and the adjacent territorial sea. Enforcing temporary safety zones for each offshore exploration or support vessel while they are on the navigable waters in the Port of Dutch Harbor or the adjacent territorial sea will help ensure the safety of all vessels, including the diverse commercial fleets of Dutch Harbor.

In evaluating this request, the Coast Guard explored relevant safety factors and considered several criteria, including, but not limited to: (1) The amount of commercial activity in and around the Port of Dutch Harbor; (2) safety concerns for personnel aboard the vessels; (3) sensitivity of the environment in the region and potential adverse affects caused by a grounding, allision, or collision; (4) the types and volume of vessels navigating in the vicinity of the Port of Dutch Harbor; and (5) the need to allow for lawful demonstrations without endangering the safe operations of support vessels. Vessels transiting in the vicinity of the proposed safety zones could consist of large commercial shipping vessels, fishing vessels, tugs and tows, and recreational vessels. Any group or individual intending to conduct lawful demonstrations in the vicinity of offshore exploration support vessels must do so outside of the temporary safety zones.

Results from a thorough and comprehensive examination of the five criteria identified above, in conjunction with International Maritime Organization guidelines and existing regulations, warrant establishment of temporary safety zones. These would significantly reduce the threat of

collisions, allisions, or other incidents which could endanger the safety of all vessels operating on the navigable waters of the Port of Dutch Harbor and the adjacent territorial sea.

**D. Discussion of Proposed Rule**

For the reasons described above, the Coast Guard is proposing temporary safety zones that would surround the designated vessels while at anchor, moored or underway on the navigable waters of the Port of Dutch Harbor and the adjacent territorial sea in order to mitigate the potential safety risks associated with the increased vessel traffic. The proposed temporary safety zones would encompass the waters within 25 yards of the support vessel if the support vessel is moored or at anchor, and 100 yards if the support vessel is in transit.

The proposed temporary safety zones would be located around moored or moving vessels in the Port of Dutch Harbor, Broad Bay or adjacent navigable waters encompassed within the area from Cape Cheerful at 54–001 N 166–38.000 W, north to the limits of the U.S. territorial sea at 54–13.000 N 166–38.000 W, and from Princess Head at 53–59.000 N 166–25.900 W, north to the limits of the U.S. territorial sea at 54–12.619 N 166–25.883 W.

The proposed temporary safety zones would prohibit entry into the zones unless specifically authorized by the Captain of the Port, Western Alaska, or his designated on-scene representative. The zones would be in effect from June 15 through July 1 to accommodate the expected arrival of the vessels.

**E. Regulatory Analyses**

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

*1. Regulatory Planning and Review*

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. The safety zone will have negligible economic impact, as there will be ample room for navigation around it.

*2. Impact on Small Entities*

The proposed rule is not a significant regulatory action due to the minimal impact this will have on standard vessel operations within the port of Dutch Harbor because of the limited area affected and the limited duration of the rule. The proposed safety zones are also designed to allow vessels transiting through the area to safely travel around the proposed safety zones without incurring additional costs.

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

This proposed rule could affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit through or anchor in within a portion of the Port of Dutch Harbor or adjacent waters, from June 15, 2015, to July 15, 2015.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons: These safety zone restrictions are only effective from June 15, 2015, to July 15, 2015, and are limited only to waters within 25 yards of the support vessel if the support vessel is moored or at anchor, and 100 yards if the support vessel is in transit.

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

*3. Assistance for Small Entities*

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rulemaking would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT,** above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

*4. Collection of Information*

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

*5. Federalism*

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

*6. Protest Activities*

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

*7. Unfunded Mandates Reform Act*

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

*8. Taking of Private Property*

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

*9. Civil Justice Reform*

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

*10. Protection of Children From Environmental Health Risks*

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

*11. Indian Tribal Governments*

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

*12. Energy Effects*

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

*13. Technical Standards*

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

*14. Environment*

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. Specifically, the proposed rule involves establishing a safety zone, which is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

**List of Subjects in 33 CFR Part 165**

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

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

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS.

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

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T17–0246 to read as follows:

**§ 165.T17–0246 Safety Zone; Port of Dutch Harbor; Dutch Harbor, Alaska.**

(a) Location. The following areas are safety zones:

(1) All navigable waters within a 25-yard radius of a moored or anchored offshore exploration or support vessel, or within a 100-yard radius of any underway offshore exploration or support vessel, located within the Port of Dutch Harbor, Broad Bay or adjacent navigable waters encompassed within the area from Cape Cheerful at 54–001 N 166–38.000 W, north to the limits of the U.S. territorial sea at 54–13.000 N 166–38.000 W, and from Princess Head at 53–59.000 N 166–25.900 W, north to the limits of the U.S. territorial sea at 54–12.619 N 166–25.883 W.

(b) Effective date. The temporary safety zones become effective at 12:01 a.m., June 15, 2015, and terminate on 11:59 p.m., July 1, 2015, unless sooner terminated by the Captain of the Port.

(c) Regulations. The general regulations governing safety zones contained in § 165.23 apply to all vessels operating within the area described in paragraph (a).

(1) If a non-exploration or support vessel is moored or anchored and an offshore exploration or support vessel transits near them such that it places the moored or anchored vessel within the 100-yard safety zone described in paragraph (a), the moored or anchored vessel must remain stationary until the offshore exploration or support vessel maneuvers to a distance exceeding the 100-yard safety zone.

(2) All persons and vessels shall comply with the instructions of the Captain of the Port (COTP) or designated on-scene representative, consisting of commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed by the COTP's designated on-scene representative.

(3) Entry into the safety zone is prohibited unless authorized by the COTP or his designated on-scene representative. Any persons desiring to enter the safety zone must contact the designated on-scene representative on VHF channel 16 (156.800 MHz) and receive permission prior to entering.

(4) If permission is granted to transit within the safety zone, all persons and vessels must comply with the instructions of the designated on-scene representative.

(5) The COTP, Western Alaska, will notify the maritime and general public by marine information broadcast during the period of time that the safety zones are in force by providing notice in accordance with 33 CFR 165.7.

(d) Penalties. Persons and vessels violating this rule are subject to the penalties set forth in 33. U.S.C. 1232 and 50 U.S.C. 192.

Dated: April 14, 2015.

**Paul Mehler, III,**

*Captain, U.S. Coast Guard, Captain of the Port, Western Alaska.*

[FR Doc. 2015–10216 Filed 4–30–15; 8:45 am]

BILLING CODE 9110–04–P

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

## 33 CFR Part 165

**[Docket Number USCG–2015–0267]**

**RIN 1625–AA00**

## Safety Zone—Oil Exploration Staging Area in Goodhope Bay; Kotzebue Sound, AK

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes temporary safety zones in the Port of Goodhope Bay, Alaska, and adjacent U.S. territorial sea from 12:01 a.m. local time on July 1, 2015, through 11:59 p.m. on October 15, 2015. The temporary safety zones would encompass the navigable waters within a 25-yard radius of moored or anchored offshore exploration or support vessels, and the navigable waters within a 100-yard radius of underway offshore exploration or support vessels. The purpose of the safety zones are to protect persons and vessels during an unusually high volume of vessel traffic in the Port of Goodhope Bay, Alaska, and the adjacent territorial sea due to additional vessel traffic associated with exploratory drilling operations in the Chukchi and Beaufort seas during the summer of

2015. Lawful demonstrations are permitted outside of the temporary safety zones so long as they do not endanger the safety of vessels either moored or anchored within the port, transiting through the port, or through the adjacent waters of the territorial sea.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 1, 2015.

**ADDRESSES:** You may submit comments identified by docket number USCG–2015–0267 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, 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.

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### *4. Public Meeting*

The Coast Guard does not now plan to hold a public meeting; 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 one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

## B. Regulatory History and Information

Similar safety zones were implemented in previous years when oil exploration equipment was staged in other locations in Alaska, most recently in 2012.

## C. Basis and Purpose

Based on information provided by private entities affiliated with oil exploration activities, the Coast Guard anticipates approximately eleven vessels associated with exploratory drilling operations will call upon the Port of Goodhope Bay, Alaska, en route to proposed drilling sites in the Chukchi and Beaufort. The addition of these vessels in conjunction with the high volume of traffic operating within the Port of Goodhope Bay creates a safety risk for all vessels operating therein. Such risks include reduced ability to navigate safely within the congested waterways of the port during the subject time period.

The vessels and equipment anticipated to be staged within these areas, due to their size and technical complexity, pose a safety risk to vessels that attempt to navigate too closely to them. Limited rescue capabilities are available in the area. In evaluating whether a safety zone would be appropriate, the Coast Guard explored relevant safety factors and considered several criteria, including, but not limited to: (1) The amount of commercial activity in and around the Port of Goodhope Bay; (2) safety concerns for personnel aboard the vessels; (3) sensitivity of the environment in the region and potential adverse affects caused by a grounding, allision, or collision; (4) the types and volume of vessels navigating in the

vicinity of the Port of Goodhope Bay; and (5) the need to allow for lawful demonstrations without endangering the safe operations of support vessels. Vessels transiting in the vicinity of the proposed safety zones could consist of large commercial shipping vessels, fishing vessels, tugs and tows, and recreational vessels. Any group or individual intending to conduct lawful demonstrations in the vicinity of offshore exploration support vessels must do so outside of the temporary safety zones. Results from a thorough and comprehensive examination of the five criteria identified above, in conjunction with International Maritime Organization guidelines and existing regulations, warrant establishment of safety zones to ensure safe and efficient vessel transits within the Port of Goodhope Bay and the adjacent territorial sea. These safety zones would facilitate safe navigation and protect vessels from hazards caused by increased volume of vessel traffic, including hazards that may be intentionally created, in the Port of Goodhope Bay.

**D. Discussion of Proposed Rule**

For the reasons described above, the Coast Guard is proposing a temporary safety zone due to safety concerns for personnel aboard the support vessels, mariners operating other vessels in the vicinity of Goodhope Bay, and to protect the environment. The proposed regulation would significantly reduce the threat of collisions, allisions, or other incidents which could endanger the safety of all vessels operating on the navigable waters of the Port of Goodhope Bay and the adjacent territorial sea. The Coast Guard proposes temporary safety zones that will prohibit entry into the zones unless specifically authorized by the Captain of the Port, Western Alaska, or his designated on-scene representative.

The proposed temporary safety zones would encompass the waters within 25 yards of the support vessel if the support vessel is moored or at anchor, and 100 yards if the support vessel is in transit. They would be in effect from July 1 through October 15, in order to encompass the expected period of operations.

**E. Regulatory Analyses**

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

*1. Regulatory Planning and Review*

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. The safety zone will have negligible economic impact, as there will be ample room for navigation around it.

*2. Impact on Small Entities*

The proposed rule is not a significant regulatory action due to the minimal impact this will have on standard vessel operations within the port of Goodhope Bay because of the limited area affected and the limited duration of the rule. The proposed safety zones are also designed to allow vessels transiting through the area to safely travel around the proposed safety zones without incurring additional costs.

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

This proposed rule could affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit through or anchor in within a portion of the Port of Goodhope Bay or adjacent waters, from July 1, 2015 to October 15, 2015.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons: These safety zone restrictions are only effective from July 1, 2015 to October 15, 2015, and are limited only to waters within 25 yards of the support vessel if the support vessel is moored or at anchor, and 100 yards if the support vessel is in transit.

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

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

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

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

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

*14. Environment*

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. Specifically, the proposed rule involves establishing a safety zone, which is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

**List of Subjects in 33 CFR Part 165**

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

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

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0171.1.

■ 2. Add § 165.T17–0267 to read as follows:

**§ 165.T17–0267 Safety Zone; Port of Goodhope Bay; Goodhope Bay, Alaska.**

(a) *Location.* The following areas are safety zones: All navigable waters within a 25-yard radius of a moored or anchored offshore exploration or support vessel, or within a 100-yard radius of any underway offshore exploration or support vessel, located within the Port of Goodhope Bay, to the limits of the U.S. territorial sea.

(b) *Effective date.* The temporary safety zones become effective at 12:01 a.m., July 1, 2015, and terminate on 11:59 p.m., October 15, 2015, unless sooner terminated by the Captain of the Port.

(c) *Regulations.* The general regulations governing safety zones contained in § 165.23 apply to all vessels operating within the area described in paragraph (a) of this section.

(1) If a non-exploration or support vessel is moored or anchored and an offshore exploration or support vessel transits near them such that it places the moored or anchored vessel within the 100-yard safety zone described in paragraph (a) of this section, the moored or anchored vessel must remain stationary until the offshore exploration or support vessel maneuvers to a distance exceeding the 100-yard safety zone.

(2) All persons and vessels shall comply with the instructions of the Captain of the Port (COTP) or designated on-scene representative, consisting of commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed by the COTP's designated on-scene representative.

(3) Entry into the safety zone is prohibited unless authorized by the COTP or his designated on-scene representative. Any persons desiring to enter the safety zone must contact the designated on-scene representative on VHF channel 16 (156.800 MHz) and receive permission prior to entering.

(4) If permission is granted to transit within the safety zone, all persons and vessels must comply with the instructions of the designated on-scene representative.

(5) The COTP, Western Alaska, will notify the maritime and general public by marine information broadcast during the period of time that the safety zones are in force by providing notice in accordance with § 165.7.

(d) *Penalties.* Persons and vessels violating this rule are subject to the penalties set forth in 33. U.S.C. 1232 and 50 U.S.C. 192.

Dated: April 14, 2015.

**Paul Mehler III,**

*Captain, U.S. Coast Guard, Captain of the Port, Western Alaska.*

[FR Doc. 2015–10234 Filed 4–30–15; 8:45 am]

**BILLING CODE 9110–04–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[EPA–R06–OAR–2015–0189; FRL–9927–12–Region 6]**

## Approval and Promulgation of Implementation Plans; Arkansas; Regional Haze and Interstate Visibility Transport Federal Implementation Plan; Extension of Comment Period and Notice of Availability

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

**ACTION:** Proposed rule; extension of comment period; availability of supplemental information.

**SUMMARY:** The Environmental Protection Agency (EPA) is extending the comment period for a proposed rule to establish a Clean Air Act (CAA) Federal Implementation Plan (FIP) to address regional haze and visibility transport requirements for the State of Arkansas.

EPA is extending the public comment period until July 15, 2015. The extension also is to allow comments on EPA supplemental modeling for the Entergy Independence plant.

**DATES:** The comment period for the proposed rule published April 8, 2015 (80 FR 18944), is extended. Written comments must be received on or before July 15, 2015.

**ADDRESSES:** Submit your comments, identified by Docket No. EPA–R06–OAR–2015–0189, by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: R6AIR_ARHaze@epa.gov.*
- *Mail:* Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.
- *Hand or Courier Delivery:* Guy Donaldson at the address above. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays, and not on legal holidays. Special arrangements should be made for deliveries of boxed information.
- *Fax:* Guy Donaldson at (214) 665–7263.

*Instructions:* Direct your comments to Docket No. EPA–R06–OAR–2015–0189. Our policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to us without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, we recommend that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If we cannot read your comment due to technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

**FOR FURTHER INFORMATION CONTACT:** Dayana Medina, (214) 665–7241; *medina.dayana@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Medina.

**SUPPLEMENTARY INFORMATION:** On April 8, 2015, we published in the **Federal Register** a proposal to establish a FIP for the State of Arkansas addressing regional haze and visibility transport (80 FR 18944). The proposed FIP includes emission limits for sources. Comments on the proposed rule were required to be received by May 16, 2015. We are extending the comment period until July 15, 2015. This action will allow interested persons additional time to prepare and submit comments.

We are also announcing the availability in the docket of supplemental modeling performed by EPA since the proposed rule for the Entergy Independence plant. Below is a summary of the supplemental modeling performed by EPA.

SUMMARY OF SUPPLEMENTAL REGIONAL HAZE MODELING FOR THE ENTERGY INDEPENDENCE PLANT

| Class I area | Visibility improvement over baseline (deciviews) | Visibility improvement of low $NO_X$ burners/separated overfire air over baseline (deciviews) |
|---|---|---|
| | Dry flue gas desulfurization | Low $NO_X$ burner |
| Caney Creek | 1.096 | 0.459 |
| Upper Buffalo | 1.178 | 0.198 |
| Hercules-Glades | 1.056 | 0.173 |
| Mingo | 1.045 | 0.148 |

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Best available control technology, Incorporation by reference, Intergovernmental relations, Interstate transport of pollution, Nitrogen dioxide, Ozone, Particulate matter, Regional haze, Reporting and recordkeeping requirements, Sulfur dioxides, Visibility.

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

Dated: April 23, 2015.

**Wren Stenger,**

*Multimedia Planning and Permitting Division Director, Region 6.*

[FR Doc. 2015–10241 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 52 and 81**

**[EPA–R03–OAR–2015–0050; FRL–9927–03–Region 3]**

# Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Redesignation Request and Associated Maintenance Plan for the Lancaster Nonattainment Area for the 1997 Annual and 2006 24-Hour Fine Particulate Matter Standard

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve the Commonwealth of Pennsylvania's April 30, 2014 request to redesignate to attainment the Lancaster nonattainment area (Lancaster Area or Area) for both the 1997 annual and the 2006 24-hour fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS or standards). EPA is also proposing to determine that the Area continues to attain the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. In addition, EPA is proposing to approve as a revision to the Pennsylvania State Implementation Plan (SIP) the associated maintenance plan that was submitted with the redesignation request, to show maintenance of the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS through 2025 for the Area. The maintenance plan includes the 2017 and 2025 $PM_{2.5}$ and nitrogen oxides ($NO_X$) motor vehicle emissions budgets (MVEBs) for the Area for both NAAQS, which EPA is proposing to approve for transportation conformity purposes. Furthermore, EPA is proposing to approve as a revision to the Pennsylvania SIP the 2007 emissions inventory that is also included in the maintenance plan for the Area for both NAAQS. This rulemaking action to propose approval of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS redesignation request and associated maintenance plan for the Lancaster Area is based on EPA's determination that Pennsylvania has met the criteria for redesignation to attainment specified in the Clean Air Act (CAA) for both NAAQS.

**DATES:** Written comments must be received on or before June 1, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA–R03–OAR–2015–0050 by one of the following methods:

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

B. *Email: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2015–0050, Cristina Fernandez, Associate Director, Office of Air Quality Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA–R03–OAR–2015–0050. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

**FOR FURTHER INFORMATION CONTACT:** Leslie Jones Doherty, (215) 814–3409 or by email at *jones.leslie@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

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## I. Background

The first air quality standards for $PM_{2.5}$ were established on July 16, 1997 (62 FR 38652, July 18, 1997). EPA promulgated an annual standard at a level of 15 micrograms per cubic meter ($\mu g/m^3$), based on a three-year average of annual mean $PM_{2.5}$ concentrations (the 1997 annual $PM_{2.5}$ NAAQS). In the same rulemaking action, EPA promulgated a 24-hour standard of 65 $\mu g/m^3$, based on a three-year average of the 98th percentile of 24-hour concentrations.

On January 5, 2005 (70 FR 944), EPA published air quality area designations for the 1997 $PM_{2.5}$ NAAQS. In that rulemaking action, EPA designated the Lancaster Area as nonattainment for the 1997 annual $PM_{2.5}$ NAAQS. *Id.* at 1000. The Lancaster Area is comprised of Lancaster County in Pennsylvania. *See* 40 CFR 81.339 (Pennsylvania).

On October 17, 2006 (71 FR 61144), EPA retained the annual average standard at 15 $\mu g/m^3$, but revised the 24-hour standard to 35 $\mu g/m^3$, based again on the three-year average of the 98th percentile of 24-hour concentrations (the 2006 24-hour $PM_{2.5}$ NAAQS). On November 13, 2009 (74 FR 58688), EPA published designations for the 2006 24-hour $PM_{2.5}$ NAAQS, which became effective on December 14, 2009. In that

rulemaking action, EPA designated the Lancaster Area as nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS. *See* 40 CFR 81.339 (Pennsylvania). This proposed rulemaking actions address the redesignations to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS for the Lancaster Area.

On September 25, 2009 (74 FR 48863) and March 29, 2012 (77 FR 18922), EPA made determinations that the Lancaster Area had attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, respectively. Pursuant to 40 CFR 51.1004(c) and based on these determinations, the requirements for the Lancaster Area to submit an attainment demonstration and associated reasonably available control measures (RACM), a reasonable further progress (RFP) plan, contingency measures, and other planning SIPs related to the attainment of either the 1997 annual or 2006 24-hour $PM_{2.5}$ NAAQS are suspended until such time as: The Area is redesignated to attainment for each standard, at which time the requirements no longer apply; or EPA determines that the Area has again violated any of the standards, at which time such plans are required to be submitted. On July 29, 2011 (76 FR 45424), EPA also determined, in accordance with section 179(c) of the CAA, that the Lancaster Area attained the 1997 annual $PM_{2.5}$ NAAQS by its applicable attainment date of April 5, 2010.

On April 30, 2014, the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), formally submitted a request to redesignate the Lancaster Area from nonattainment to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. Concurrently, PADEP submitted a combined maintenance plan for the Area as a SIP revision to ensure continued attainment throughout the Area over the next 10 years. The maintenance plan includes the 2017 and 2025 $PM_{2.5}$ and $NO_X$ MVEBs for the Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. Also included in the maintenance plan is the 2007 comprehensive emissions inventory for both the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS for $PM_{2.5}$, $NO_X$, sulfur dioxide ($SO_2$), volatile organic compounds (VOCs), and ammonia ($NH_3$).

In this proposed rulemaking action, EPA also addresses the effects of several decisions of the United States Court of Appeals for the District of Columbia (D.C. Circuit Court) and a decision of the United States Supreme Court: (1) The D.C. Circuit Court's August 21, 2012 decision to vacate and remand to EPA the Cross-State Air Pollution Control Rule (CSAPR); (2) the Supreme Court's April 29, 2014 reversal of the vacature of CSAPR, and remand to the D.C. Circuit Court; (3) the D.C. Circuit Court's October 23, 2014 decision to lift the stay of CSAPR; and (4) the D.C. Circuit Court's January 4, 2013 decision to remand to EPA two final rules implementing the 1997 annual $PM_{2.5}$ NAAQS.

## II. EPA's Requirements

### *A. Criteria for Redesignation to Attainment*

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation providing that: (1) EPA determines that the area has attained the applicable NAAQS; (2) EPA has fully approved the applicable implementation plan for the area under section 110(k); (3) EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable Federal air pollutant control regulations and other permanent and enforceable reductions; (4) EPA has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA; and (5) the state containing such area has met all requirements applicable to the area under section 110 and part D. Each of these requirements are discussed in Section V. of this proposed rulemaking action.

EPA has provided guidance on redesignation in the ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clear Air Act Amendments of 1990,'' (57 FR 13498, April 16, 1992) (the ''General Preamble'') and has provided further guidance on processing redesignation requests in the following documents: (1) ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter the ''1992 Calcagni Memorandum''); (2) ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and (3) ''Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994.

### *B. Requirements of a Maintenance Plan*

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after approval of a redesignation of an area to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the 10 years following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary to assure prompt correction of any future $PM_{2.5}$ violations.

The 1992 Calcagni Memorandum provides additional guidance on the content of a maintenance plan. The Memorandum states that a maintenance plan should address the following provisions: (1) An attainment emissions inventory; (2) a maintenance demonstration showing maintenance for 10 years; (3) a commitment to maintain an appropriate air quality monitoring network in accordance with 40 CFR part 58; (4) verification of continued attainment; and, (5) a contingency plan to prevent or correct future violations of the NAAQS.

Under the CAA, states are required to submit, at various times, control strategy SIP revisions for nonattainment areas and maintenance plans for areas seeking redesignation to attainment for a given NAAQS. These emission control strategy SIP revisions (*e.g.,* RFP and attainment demonstration SIP revisions) and maintenance plans also create MVEBs based on onroad mobile source emissions for the relevant criteria pollutants and/or their precursors, where appropriate, to address pollution from onroad transportation sources. The MVEBs are the portions of the total allowable emissions that are allocated to onroad vehicle use that, together with emissions from all other sources in the area, will provide attainment, RFP, or maintenance, as applicable. The budget serves as a ceiling on emissions from an area's planned transportation system. Under 40 CFR part 93, a MVEB for an area seeking a redesignation to attainment is established for the last year of the maintenance plan.

The maintenance plan for the Lancaster Area, which is comprised of Lancaster County in Pennsylvania,

includes the 2017 and 2025 $PM_{2.5}$ and $NO_X$ MVEBs for transportation conformity purposes. The transportation conformity determination for the Area is further discussed in Section V.C. of this proposed rulemaking action and in a technical support document (TSD), ''Adequacy Findings for the Motor Vehicle Emissions Budgets in the Maintenance Plan for the Lancaster 1997 and 2006 Fine Particulate National Ambient Air Quality Standard Nonattainment Area,'' dated 2/25/15, available on line at *www.regulations.gov,* Docket ID No. EPA–R03–OAR–2015–0050.

## III. Summary of Proposed Actions

EPA is proposing to take several rulemaking actions related to the redesignation of the Lancaster Area to attainment for both the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. EPA is proposing to find that the Lancaster Area meets the requirements for redesignation of the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS under section 107(d)(3)(E) of the CAA. EPA is thus proposing to approve Pennsylvania's request to change the legal designation of the Lancaster Area from nonattainment to attainment for both the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. EPA is also proposing to approve the associated maintenance plan for the Lancaster Area as a revision to the Pennsylvania SIP for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, including the 2017 and 2025 $PM_{2.5}$ and $NO_X$ MVEBs for the Area for transportation conformity purposes. Approval of the maintenance plan is one of the CAA criteria for redesignation of the Area to attainment for both NAAQS. Pennsylvania's combined maintenance plan is designed to ensure continued attainment of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in the Area for at least 10 years after redesignation.

EPA previously determined that the Lancaster Area attained both the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS (*see* 74 FR 48863 (September 25, 2009) and 77 FR 18922 (March 29, 2012)), and EPA is proposing to find that the Area continues to attain both NAAQS. EPA is also proposing to approve the 2007 comprehensive emissions inventory submitted with Pennsylvania's maintenance plan that includes an inventory of $PM_{2.5}$, $SO_2$, $NO_X$, VOC, and $NH_3$ for the Area as a revision to the Pennsylvania SIP for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in order to meet the requirements of section 172(c)(3) of the CAA. EPA's analysis of the proposed actions is provided in Section V. of this proposed rulemaking.

## IV. Effects of Recent Court Decisions on Proposed Actions

### *A. Effect of the Court Decision Regarding EPA's CSAPR*

1. Background

The D.C. Circuit Court and the Supreme Court have issued a number of decisions and orders regarding the status of EPA's regional trading programs for transported air pollution, the Clean Air Interstate Rule (CAIR) and CSAPR, that impact this proposed redesignation action. In 2008, the D.C, Circuit Court initially vacated CAIR, *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina* v. *EPA,* 550 F.3d 1176, 1178 (D.C. Cir. 2008). On August 8, 2011 (76 FR 48208), acting on the D.C. Circuit Court's remand, EPA promulgated CSAPR, to address interstate transport of emissions and resulting secondary air pollutants and to replace CAIR.[1] CSAPR requires substantial reductions of $SO_2$ and $NO_X$ emissions from electric generating units (EGUs) in 28 states in the Eastern United States. Implementation of CSAPR was scheduled to begin on January 1, 2012, when CSAPR's cap-and-trade programs would have superseded the CAIR cap-and-trade programs. Numerous parties filed petitions for review of CSAPR, and on December 30, 2011, the D.C. Circuit Court issued an order staying CSAPR pending resolution of the petitions and directing EPA to continue to administer CAIR. *EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302 (D.C. Cir. Dec. 30, 2011), Order at 2.

On August 21, 2012, the D.C. Circuit Court issued its ruling, vacating and remanding CSAPR to EPA and once again ordering continued implementation of CAIR. *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7, 38 (D.C. Cir. 2012). The D.C. Circuit Court subsequently denied EPA's petition for rehearing en banc. *EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302, 2013 WL 656247 (D.C. Cir. Jan. 24, 2013), at *1. EPA and other parties then petitioned the Supreme Court for a writ of certiorari, and the Supreme Court granted the petitions on June 24, 2013. *EPA* v. *EME Homer City Generation, L.P.,* 133 S. Ct. 2857 (2013).

On April 29, 2014, the Supreme Court vacated and reversed the D.C. Circuit Court's decision regarding CSAPR, and remanded that decision to the D.C. Circuit Court to resolve remaining issues in accordance with its ruling. *EPA* v. *EME Homer City Generation, L.P.,* 134 S. Ct. 1584 (2014). EPA moved to have the stay of CSAPR lifted in light of the Supreme Court decision. *EME Homer City Generation, L.P.* v. *EPA,* Case No. 11–1302, Document No. 1499505 (D.C. Cir. filed June 26, 2014). In its motion, EPA asked the D.C. Circuit Court to toll CSAPR's compliance deadlines by three years, so that the Phase 1 emissions budgets apply in 2015 and 2016 (instead of 2012 and 2013), and the Phase 2 emissions budgets apply in 2017 and beyond (instead of 2014 and beyond). On October 23, 2014, the D.C. Circuit Court granted EPA's motion and lifted the stay of CSAPR which was imposed on December 30, 2011. *EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302 (D.C. Cir. Oct. 23, 2014), Order at 3. On December 3, 2014, EPA issued an interim final rule to clarify how EPA will implement CSAPR consistent with the D.C. Circuit Court's order granting EPA's motion requesting lifting the stay and tolling the rule's deadlines. *See* 79 FR 71663 (December 3, 2014) (interim final rulemaking). Consistent with that rule, EPA began implementing CSAPR on January 1, 2015.

2. Proposal on This Issue

Because CAIR was promulgated in 2005 and incentivized sources and states to begin achieving early emission reductions, the air quality data examined by EPA in issuing a final determination of attainment for the Lancaster Area in 2009 (September 25, 2009, 74 FR 48863) and the air quality data from the Area since 2005 necessarily reflect reductions in emissions from upwind sources as a result of CAIR, and Pennsylvania includes CAIR as one of the measures that helped to bring the Area into attainment. However, modeling conducted by EPA during the CSAPR rulemaking process, which used a baseline emissions scenario that ''backed out'' the effects of CAIR, *see* 76 FR 48223, projected that the Lancaster Area would have design values below the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS for 2012 and 2014 without taking into account emission reductions from CAIR or CSAPR. *See* Appendix B of EPA's ''Air Quality Modeling Final Rule Technical Support Document,'' (Pages B–57 and B–86),

[1] CAIR addressed the 1997 annual $PM_{2.5}$ NAAQS and the 1997 8-hour ozone NAAQS. CSAPR addresses contributions from upwind states to downwind nonattainment and maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS as well as the ozone and $PM_{2.5}$ NAAQS addressed by CAIR.

which is available in the docket for this proposed rulemaking action. In addition, the 2011–2013 quality-assured, quality-controlled, and certified monitoring data for the Lancaster Area confirms that the $PM_{2.5}$ annual design value for the Area remained well below the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in 2013.

The status of CSAPR is not relevant to this redesignation. CSAPR was promulgated in June 2011, and the rule was stayed by the D.C. Circuit Court just six months later, before the trading programs it created were scheduled to go into effect. As stated previously, EPA began implementing CSAPR on January 1, 2015, subsequent to the emission reductions documented in the Commonwealth's April 30, 2014 request for redesignation. Therefore, the Area's attainment of the 1997 annual or the 2006 24-hour $PM_{2.5}$ NAAQS cannot have been a result of any emission reductions associated with CSAPR. In summary, neither the status of CAIR nor the current status of CSAPR affects any of the criteria for proposed approval of this redesignation request for the Lancaster Area.

*B. Effect of the D.C. Circuit Court Decision Regarding $PM_{2.5}$ Implementation Under Subpart 4 of Part D of Title I of the CAA*

1. Background

On January 4, 2013, in *NRD.C.* v. *EPA,* the D.C. Circuit Court remanded to EPA the ''Final Clean Air Fine Particle Implementation Rule'' (72 FR 20586, April 25, 2007) and the ''Implementation of the New Source Review (NSR) Program for $PM_{2.5}$'' final rule (73 FR 28321, May 16, 2008) (collectively, ''1997 $PM_{2.5}$ Implementation Rule''). 706 F.3d 428 (D.C. Cir. 2013). The D.C. Circuit Court found that EPA erred in implementing the 1997 annual $PM_{2.5}$ NAAQS pursuant to the general implementation provisions of subpart 1 of Part D of Title I of the CAA (subpart 1), rather than the particulate-matter-specific provisions of subpart 4 of Part D of Title I (subpart 4).

Prior to the January 4, 2013 decision, the states had worked towards meeting the air quality goals of the 1997 and 2006 $PM_{2.5}$ NAAQS in accordance with EPA regulations and guidance derived from subpart 1 of Part D of Title I of the CAA. In response to the D.C. Circuit Court's remand, EPA took this history into account by setting a new deadline for any remaining submissions that may be required for moderate nonattainment areas as a result of the D.C. Circuit Court's decision regarding the applicability of subpart 4 of Part D of Title I of the CAA.

On June 2, 2014 (79 FR 31566), EPA issued a final rule, ''Identification of Nonattainment Classification and Deadlines for Submission of SIP Provisions for the 1997 and 2006 $PM_{2.5}$ NAAQS'' (the $PM_{2.5}$ Subpart 4 Classification and Deadline Rule), which identifies the classification under subpart 4 as ''moderate'' for areas currently designated nonattainment for the 1997 annual and/or 2006 24-hour $PM_{2.5}$ NAAQS. The rule sets a deadline for states to submit attainment plans and meet other subpart 4 requirements. The rule specifies December 31, 2014 as the deadline for states to submit any additional attainment-related SIP elements that may be needed to meet the applicable requirements of subpart 4 for areas currently designated nonattainment for the 1997 $PM_{2.5}$ and/or 2006 $PM_{2.5}$ NAAQS and to submit SIPs addressing the nonattainment new source review (NSR) requirements in subpart 4.

As explained in detail in the following section, since Pennsylvania submitted its request to redesignate the Lancaster Area on April 30, 2014, any additional attainment-related SIP elements that may be needed for the Lancaster Area to meet the applicable requirements of subpart 4 were not due at the time Pennsylvania submitted its request to redesignate the Area for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS.

2. Proposal on This Issue

In this proposed rulemaking action, EPA addresses the effect of the D.C. Circuit Court's January 4, 2013 decision and the June 2, 2014 $PM_{2.5}$ Subpart 4 Classification and Deadline Rule on the redesignation requests for the Area. EPA is proposing to determine that the D.C. Circuit Court's January 4, 2013 decision does not prevent EPA from redesignating the Area to attainment for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. Even in light of the D.C. Circuit Court's decision, redesignation for this Area is appropriate under the CAA and EPA's longstanding interpretations of the CAA's provisions regarding redesignation. EPA first explains its longstanding interpretation that requirements that are imposed, or that become due, after a complete redesignation request is submitted for an area that is attaining the standard, are not applicable for purposes of evaluating a redesignation request. Second, EPA then shows that, even if EPA applies the subpart 4 requirements to the redesignation requests of the Area and disregards the provisions of its 1997 $PM_{2.5}$ Implementation Rule recently remanded by the D.C. Circuit Court, Pennsylvania's request for redesignation of the Area still qualifies for approval. EPA's discussion also takes into account the effect of the D.C. Circuit Court's ruling and the June 2, 2014 $PM_{2.5}$ Subpart 4 Classification and Deadline Rule on the maintenance plans of the Area, which EPA views as approvable even when subpart 4 requirements are considered.

a. Applicable Requirements Under Subpart 4 for Purposes of Evaluating the Redesignation Request of the Area

With respect to the 1997 $PM_{2.5}$ Implementation Rule, the D.C. Circuit Court's January 4, 2013 ruling rejected EPA's reasons for implementing the $PM_{2.5}$ NAAQS solely in accordance with the provisions of subpart 1, and remanded that matter to EPA, so that it could address implementation of the 1997 annual $PM_{2.5}$ NAAQS under subpart 4 of Part D of the CAA, in addition to subpart 1. For the purposes of evaluating Pennsylvania's redesignation requests for the Area, to the extent that implementation under subpart 4 would impose additional requirements for areas designated nonattainment, EPA believes that those requirements are not ''applicable'' for the purposes of section 107(d)(3)(E) of the CAA, and thus EPA is not required to consider subpart 4 requirements with respect to the redesignation of the areas. Under its longstanding interpretation of the CAA, EPA has interpreted section 107(d)(3)(E) to mean, as a threshold matter, that the part D provisions which are ''applicable'' and which must be approved in order for EPA to redesignate an area include only those which came due prior to a state's submittal of a complete redesignation request. *See* 1992 Calcagni Memorandum. *See also* ''SIP Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) NAAQS on or after November 15, 1992,'' Memorandum from Michael Shapiro, Acting Assistant Administrator, Air and Radiation, September 17, 1993 (Shapiro memorandum); Final Redesignation of Detroit-Ann Arbor, (60 FR 12459, 12465–66, March 7, 1995); Final Redesignation of St. Louis, Missouri, (68 FR 25418, 25424–27, May 12, 2003); *Sierra Club* v. *EPA,* 375 F.3d 537, 541 (7th Cir. 2004) (upholding EPA's redesignation rulemaking applying this interpretation and expressly rejecting Sierra Club's view that the meaning of ''applicable'' under the statute is ''whatever should have been in the plan

at the time of attainment rather than whatever actually was in the plan and already implemented or due at the time of attainment'').[2] In this case, at the time that Pennsylvania submitted its redesignation request for the 1997 and the 2006 24-hour $PM_{2.5}$ NAAQS, the requirements under subpart 4 were not due.[3]

EPA's view that, for purposes of evaluating the redesignation of the Pennsylvania portion of the Area, the subpart 4 requirements were not due at the time Pennsylvania submitted the redesignation request is in keeping with the EPA's interpretation of subpart 2 requirements for subpart 1 ozone areas redesignated subsequent to the D.C. Circuit Court's decision in *South Coast Air Quality Mgmt. Dist.* v. *EPA,* 472 F.3d 882 (D.C. Cir. 2006). In *South Coast,* the D.C. Circuit Court found that EPA was not permitted to implement the 1997 8-hour ozone standard solely under subpart 1, and held that EPA was required under the statute to implement the standard under the ozone-specific requirements of subpart 2 as well. Subsequent to the *South Coast* decision, in evaluating and acting upon redesignation requests for the 1997 8-hour ozone standard that were submitted to EPA for areas under subpart 1, EPA applied its longstanding interpretation of the CAA that ''applicable requirements,'' for purposes of evaluating a redesignation, are those that had been due at the time the redesignation request was submitted. *See, e.g.,* Proposed Redesignation of Manitowoc County and Door County Nonattainment Areas (75 FR 22047, 22050, April 27, 2010). In those rulemaking actions, EPA therefore, did not consider subpart 2 requirements to be ''applicable'' for the purposes of evaluating whether the area should be redesignated under section 107(d)(3)(E) of the CAA.

EPA's interpretation derives from the provisions of section 107(d)(3) of the CAA. Section 107(d)(3)(E)(v) states that, for an area to be redesignated, a state must meet ''all requirements 'applicable' to the area under section 110 and part D.'' Section 107(d)(3)(E)(ii) provides that EPA must have fully approved the ''applicable'' SIP for the area seeking redesignation. These two sections read together support EPA's interpretation of ''applicable'' as only those requirements that came due prior to submission of a complete redesignation request.

First, holding states to an ongoing obligation to adopt new CAA requirements that arose after the state submitted its redesignation request, in order to be redesignated, would make it problematic or impossible for EPA to act on redesignation requests in accordance with the 18-month deadline Congress set for EPA action in section 107(d)(3)(D). If ''applicable requirements'' were interpreted to be a continuing flow of requirements with no reasonable limitation, states, after submitting a redesignation request, would be forced continuously to make additional SIP submissions that in turn would require EPA to undertake further notice-and-comment rulemaking actions to act on those submissions. This would create a regime of unceasing rulemaking that would delay action on the redesignation request beyond the 18-month timeframe provided by the CAA for this purpose.

Second, a fundamental premise for redesignating a nonattainment area to attainment is that the area has attained the relevant NAAQS due to emission reductions from existing controls. Thus, an area for which a redesignation request has been submitted would have already attained the NAAQS as a result of satisfying statutory requirements that came due prior to the submission of the request. Absent a showing that unadopted and unimplemented requirements are necessary for future maintenance, it is reasonable to view the requirements applicable for purposes of evaluating the redesignation request as including only those SIP requirements that have already come due. These are the requirements that led to attainment of the NAAQS. To require, for redesignation approval, that a state also satisfy additional SIP requirements coming due after the state submits its complete redesignation request, and while EPA is reviewing it, would compel the state to do more than is necessary to attain the NAAQS, without a showing that the additional requirements are necessary for maintenance.

In the context of this redesignation, the timing and nature of the D.C. Circuit Court's January 4, 2013 decision in *NRDC* v. *EPA* and EPA's June 2, 2014 $PM_{2.5}$ Subpart 4 Classification and Deadline Rule, compound the consequences of imposing requirements that come due after the redesignation request is submitted. Pennsylvania submitted its redesignation request for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS on April 30, 2014 for the Lancaster Area, which is prior to the deadline by which the Area is required to meet the attainment plan and other requirements pursuant to subpart 4.

To require Pennsylvania's fully-complete and pending redesignation request for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS to comply now with requirements of subpart 4 that the D.C. Circuit Court announced only in January 2013 and for which the deadline to comply had not yet come prior to submission of its request, would be to give retroactive effect to such requirements and provide Pennsylvania a unique and earlier deadline for compliance solely on the basis of submitting its redesignation requests for the Area. The D.C. Circuit Court recognized the inequity of this type of retroactive impact in *Sierra Club* v. *Whitman,* 285 F.3d 63 (D.C. Cir. 2002),[4] where it upheld the D.C. Circuit Court's ruling refusing to make retroactive EPA's determination that the areas did not meet their attainment deadlines. In that case, petitioners urged the D.C. Circuit Court to make EPA's nonattainment determination effective as of the date that the statute required, rather than the later date on which EPA actually made the determination. The D.C. Circuit Court rejected this view, stating that applying it ''would likely impose large costs on States, which would face fines and suits for not implementing air pollution prevention plans . . . even though they were not on notice at the time.'' *Id.* at 68. Similarly, it would be unreasonable to penalize Pennsylvania by rejecting its redesignation request for an area that is already attaining the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS and that met all applicable requirements known to be in effect at the time of the request. For EPA now to reject the redesignation request solely because Pennsylvania did not expressly address subpart 4 requirements which came due after receipt of such request, would inflict the same unfairness condemned by the D.C. Circuit Court in *Sierra Club* v. *Whitman.*

[2] Applicable requirements of the CAA that come due subsequent to the area's submittal of a complete redesignation request remain applicable until a redesignation is approved, but are not required as a prerequisite to redesignation. Section 175A(c) of the CAA.

[3] EPA found Pennsylvania's April 30, 2014 submittal for redesignation of the Area complete on September 23, 2014. EPA's completeness determination is available in the docket for this rulemaking at regulations.gov, Docket ID No. EPA–R03–OAR–2015–0050.

[4] *Sierra Club* v. *Whitman* was discussed and distinguished in a recent D.C. Circuit Court decision that addressed retroactivity in a quite different context, where, unlike the situation here, EPA sought to give its regulations retroactive effect. *National Petrochemical and Refiners Ass'n* v. *EPA.* 630 F.3d 145, 163 (D.C. Cir. 2010), rehearing denied 643 F.3d 958 (D.C. Cir. 2011), cert denied 132 S. Ct. 571 (2011).

b. Subpart 4 Requirements and Pennsylvania's Redesignation Request

Even if EPA were to take the view that the D.C. Circuit Court's January 4, 2013 decision, or the June 2, 2014 $PM_{2.5}$ Subpart 4 Classification and Deadline Rule, requires that, in the context of a pending redesignation request for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS, which were submitted prior to December 31, 2014, subpart 4 requirements must be considered as being due and in effect, EPA proposes to determine that the Area still qualifies for redesignation to attainment for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. As explained subsequently, EPA believes that the redesignation request for the Area, though not expressed in terms of subpart 4 requirements, substantively meets the requirements of that subpart for purposes of redesignating the Area to attainment for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. With respect to evaluating the relevant substantive requirements of subpart 4 for purposes of redesignating the Area, EPA notes that subpart 4 incorporates components of subpart 1 of part D, which contains general air quality planning requirements for areas designated as nonattainment. *See* section 172(c). Subpart 4 itself contains specific planning and scheduling requirements for coarse particulate matter ($PM_{10}$)[5] nonattainment areas, and under the D.C. Circuit Court's January 4, 2013 decision in *NRDC* v. *EPA,* these same statutory requirements also apply for $PM_{2.5}$ nonattainment areas. EPA has longstanding general guidance that interprets the 1990 amendments to the CAA, making recommendations to states for meeting the statutory requirements for SIPs for nonattainment areas. *See* the General Preamble. In the General Preamble, EPA discussed the relationship of subpart 1 and subpart 4 SIP requirements, and pointed out that subpart 1 requirements were to an extent ''subsumed by, or integrally related to, the more specific $PM_{10}$ requirements'' (57 FR 13538, April 16, 1992). The subpart 1 requirements include, among other things, provisions for attainment demonstrations, RACM, RFP, emissions inventories, and contingency measures.

For the purposes of this redesignation request, in order to identify any additional requirements which would apply under subpart 4, consistent with EPA's June 2, 2014 $PM_{2.5}$ Subpart 4 Classification and Deadline Rule, EPA is considering the areas to be ''moderate'' $PM_{2.5}$ nonattainment areas. As EPA explained in its June 2, 2014 rule, section 188 of the CAA provides that all areas designated nonattainment areas under subpart 4 are initially to be classified by operation of law as ''moderate'' nonattainment areas, and remain moderate nonattainment areas unless and until EPA reclassifies the area as a ''serious'' nonattainment area. Accordingly, EPA believes that it is appropriate to limit the evaluation of the potential impact of subpart 4 requirements to those that would be applicable to moderate nonattainment areas. Sections 189(a) and (c) of subpart 4 apply to moderate nonattainment areas and include the following: (1) An approved permit program for construction of new and modified major stationary sources (section 189(a)(1)(A)); (2) an attainment demonstration (section 189(a)(1)(B)); (3) provisions for RACM (section 189(a)(1)(C)); and (4) quantitative milestones demonstrating RFP toward attainment by the applicable attainment date (section 189(c)).

The permit requirements of subpart 4, as contained in section 189(a)(1)(A), refer to and apply the subpart 1 permit provisions requirements of sections 172 and 173 to $PM_{10}$, without adding to them. Consequently, EPA believes that section 189(a)(1)(A) does not itself impose for redesignation purposes any additional requirements for moderate areas beyond those contained in subpart 1.[6] In any event, in the context of redesignation, EPA has long relied on the interpretation that a fully approved nonattainment NSR program is not considered an applicable requirement for redesignation, provided the area can maintain the standard with a prevention of significant deterioration (PSD) program after redesignation. A detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, ''Part D NSR Requirements for Areas Requesting Redesignation to Attainment.'' *See also* rulemakings for Detroit, Michigan (60 FR 12467–12468, March 7, 1995); Cleveland-Akron-Lorain, Ohio (61 FR 20458, 20469–20470, May 7, 1996); Louisville, Kentucky (66 FR 53665, October 23, 2001); and Grand Rapids, Michigan (61 FR 31834–31837, June 21, 1996).

With respect to the specific attainment planning requirements under subpart 4,[7] when EPA evaluates a redesignation request under either subpart 1 or 4, any area that is attaining the $PM_{2.5}$ NAAQS is viewed as having satisfied the attainment planning requirements for these subparts. For redesignations, EPA has for many years interpreted attainment-linked requirements as not applicable for areas attaining the standard. In the General Preamble, EPA stated that: ''The requirements for RFP will not apply in evaluating a request for redesignation to attainment since, at a minimum, the air quality data for the area must show that the area has already attained. Showing that the State will make RFP towards attainment will, therefore, have no meaning at that point.''

The General Preamble also explained that: ''[t]he section 172(c)(9) requirements are directed at ensuring RFP and attainment by the applicable date. These requirements no longer apply when an area has attained the standard and is eligible for redesignation. Furthermore, section 175A for maintenance plans . . . provides specific requirements for contingency measures that effectively supersede the requirements of section 172(c)(9) for these areas.'' *Id.* EPA similarly stated in its 1992 Calcagni Memorandum that, ''The requirements for reasonable further progress and other measures needed for attainment will not apply for redesignations because they only have meaning for areas not attaining the standard.''

It is evident that even if we were to consider the D.C. Circuit Court's January 4, 2013 decision in *NRDC* v. *EPA,* or the June 2, 2014 $PM_{2.5}$ Subpart 4 Classification and Deadline Rule, to mean that attainment-related requirements specific to subpart 4 were either due prior to Pennsylvania's April 30, 2014 redesignation request or became due subsequent to the April 30, 2014 redesignation request and must now be imposed retroactively,[8] those requirements do not apply to areas that are attaining the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS for the purpose of evaluating a pending request to redesignate the areas to attainment. EPA has consistently enunciated this interpretation of applicable requirements under section 107(d)(3)(E) since the General Preamble was published more than twenty years ago.

[5] $PM_{10}$ refers to particulates nominally 10 micrometers in diameter or smaller.

[6] The potential effect of section 189(e) on section 189(a)(1)(A) for purposes of evaluating this redesignation is discussed in this rulemaking action.

[7] EPA refers here to attainment demonstration, RFP, RACM, milestone requirements, and contingency measures.

[8] As explained earlier, EPA does not believe that the D.C. Circuit Court's January 4, 2013 decision should be interpreted so as to impose these requirements on the states retroactively. *Sierra Club* v. *Whitman, supra.*

Courts have recognized the scope of EPA's authority to interpret ''applicable requirements'' in the redesignation context. *See Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004).

Moreover, even outside the context of redesignations, EPA has viewed the obligations to submit attainment-related SIP planning requirements of subpart 4 as inapplicable for areas that EPA determines are attaining the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. EPA's prior ''Clean Data Policy'' rulemakings for the $PM_{10}$ NAAQS, also governed by the requirements of subpart 4, explain EPA's reasoning. They describe the effects of a determination of attainment on the attainment-related SIP planning requirements of subpart 4. *See* ''Determination of Attainment for Coso Junction Nonattainment Area,'' (75 FR 27944, May 19, 2010). *See also* Coso Junction Proposed $PM_{10}$ Redesignation, (75 FR 36023, 36027, June 24, 2010); Proposed and Final Determinations of Attainment for San Joaquin Nonattainment Area (71 FR 40952, 40954–55, July 19, 2006; and 71 FR 63641, 63643–47, October 30, 2006). In short, EPA in this context has also long concluded that to require states to meet superfluous SIP planning requirements is not necessary and not required by the CAA, so long as those areas continue to attain the relevant NAAQS.

As stated previously in this proposed rulemaking action, on September 25, 2009 (74 FR 48863) and March 29, 2012 (77 FR 18922), EPA made determinations that the Lancaster Area had attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, respectively. Pursuant to 40 CFR 51.1004(c) and based on these determinations, the requirements for the Area to submit an attainment demonstration and associated RACM, RFP plan, contingency measures, and other planning SIPs related to the attainment of either the 1997 annual or 2006 24-hour $PM_{2.5}$ NAAQS were, and continue to be, suspended until such time as: The Area is redesignated to attainment for each standard, at which time the requirements no longer apply; or EPA determines that the Area has again violated any of the standards, at which time such plans are required to be submitted. Under its longstanding interpretation, EPA is proposing to determine here that the Area meets the attainment-related plan requirements of subparts 1 and 4 for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. Thus, EPA is proposing to conclude that the requirements to submit an attainment demonstration under 189(a)(1)(B), a RACM determination under section 172(c)(1) and section 189(a)(1)(c), a RFP demonstration under 189(c)(1), and contingency measure requirements under section 172(c)(9) are satisfied for purposes of evaluating this redesignation request.

c. Subpart 4 and Control of $PM_{2.5}$ Precursors

The D.C. Circuit Court in *NRDC* v. *EPA* remanded to EPA the two rules at issue in the case with instructions to EPA to re-promulgate them consistent with the requirements of subpart 4. EPA in this section addresses the D.C. Circuit Court's opinion with respect to $PM_{2.5}$ precursors. While past implementation of subpart 4 for $PM_{10}$ has allowed for control of $PM_{10}$ precursors such as $NO_X$ from major stationary, mobile, and area sources in order to attain the standard as expeditiously as practicable, section 189(e) of the CAA specifically provides that control requirements for major stationary sources of direct $PM_{10}$ shall also apply to $PM_{10}$ precursors from those sources, except where EPA determines that major stationary sources of such precursors ''do not contribute significantly to $PM_{10}$ levels which exceed the standard in the area.''

EPA's 1997 $PM_{2.5}$ Implementation Rule, remanded by the D.C. Circuit Court, contained rebuttable presumptions concerning certain $PM_{2.5}$ precursors applicable to attainment plans and control measures related to those plans. Specifically, in 40 CFR 51.1002, EPA provided, among other things, that a state was ''not required to address VOC [and $NH_3$] as . . . $PM_{2.5}$ attainment plan precursor[s] and to evaluate sources of VOC [and $NH_3$] emissions in the State for control measures.'' EPA intended these to be rebuttable presumptions. EPA established these presumptions at the time because of uncertainties regarding the emission inventories for these pollutants and the effectiveness of specific control measures in various regions of the country in reducing $PM_{2.5}$ concentrations. EPA also left open the possibility for such regulation of VOC and $NH_3$ in specific areas where that was necessary.

The D.C. Circuit Court in its January 4, 2013 decision made reference to both section 189(e) and 40 CFR 51.1002, and stated that, ''In light of our disposition, we need not address the petitioners' challenge to the presumptions in [40 CFR 51.1002] that VOCs and $NH_3$ are not $PM_{2.5}$ precursors, as subpart 4 expressly governs precursor presumptions.'' *NRDC* v. *EPA,* at 27, n.10.

Elsewhere in the D.C. Circuit Court's opinion, however, the D.C. Circuit Court observed: ''$NH_3$ is a precursor to fine particulate matter, making it a precursor to both $PM_{2.5}$ and $PM_{10}$. For a $PM_{10}$ nonattainment area governed by subpart 4, a precursor is presumptively regulated. *See* 42 U.S.C. 7513a(e) [section 189(e)].'' *Id.* at 21, n.7.

For a number of reasons, EPA believes that its proposed redesignation of the Lancaster Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS are consistent with the D.C. Circuit Court's decision on this aspect of subpart 4. While the D.C. Circuit Court, citing section 189(e), stated that ''for a $PM_{10}$ area governed by subpart 4, a precursor is 'presumptively' regulated,'' the D.C. Circuit Court expressly declined to decide the specific challenge to EPA's 1997 $PM_{2.5}$ Implementation Rule provisions regarding $NH_3$ and VOC as precursors. The D.C. Circuit Court had no occasion to reach whether and how it was substantively necessary to regulate any specific precursor in a particular $PM_{2.5}$ nonattainment area, and did not address what might be necessary for purposes of acting upon a redesignation request.

However, even if EPA takes the view that the requirements of subpart 4 were deemed applicable at the time the state submitted the redesignation request, and disregards the 1997 $PM_{2.5}$ Implementation Rule's rebuttable presumptions regarding $NH_3$ and VOC as $PM_{2.5}$ precursors, the regulatory consequence would be to consider the need for regulation of all precursors from any sources in the Area to demonstrate attainment and to apply the section 189(e) provisions to major stationary sources of precursors. In the case of the Lancaster Area, EPA believes that doing so is consistent with proposing redesignation of the Lancaster Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. The Lancaster Area has attained the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS without any specific additional controls of $NH_3$ and VOC emissions from any sources in the Area.

Precursors in subpart 4 are specifically regulated under the provisions of section 189(e), which requires, with important exceptions, control requirements for major stationary sources of $PM_{10}$ precursors.[9] Under subpart 1 and EPA's prior implementation rule, all major stationary sources of $PM_{2.5}$ precursors were subject to regulation, with the

[9] Under either subpart 1 or subpart 4, for purposes of demonstrating attainment as expeditiously as practicable, a state is required to evaluate all economically and technologically feasible control measures for direct PM emissions and precursor emissions, and adopt those measures that are deemed reasonably available.

exception of $NH_3$ and VOC. Thus EPA must address here whether additional controls of $NH_3$ and VOC from major stationary sources are required under section 189(e) of subpart 4 in order to redesignate the Lancaster Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. As explained subsequently, EPA does not believe that any additional controls of $NH_3$ and VOC are required in the context of this redesignation.

In the General Preamble, EPA discusses its approach to implementing section 189(e). *See* 57 FR 13538–13542. With regard to precursor regulation under section 189(e), the General Preamble explicitly stated that control of VOC under other CAA requirements may suffice to relieve a state from the need to adopt precursor controls under section 189(e). *See* 57 FR 13542. EPA in this rulemaking action, proposes to determine that the Pennsylvania SIP revision has met the provisions of section 189(e) with respect to $NH_3$ and VOC as precursors. These proposed determinations are based on EPA's findings that: (1) The Lancaster Area contains no major stationary sources of $NH_3$; and (2) existing major stationary sources of VOC are adequately controlled under other provisions of the CAA regulating the ozone NAAQS.[10] In the alternative, EPA proposes to determine that, under the express exception provisions of section 189(e), and in the context of the redesignation of the Area, which is attaining the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS, at present $NH_3$ and VOC precursors from major stationary sources do not contribute significantly to levels exceeding the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS in the Area. *See* 57 FR 13539–42.

EPA notes that its 1997 $PM_{2.5}$ Implementation Rule provisions in 40 CFR 51.1002 were not directed at evaluation of $PM_{2.5}$ precursors in the context of redesignation, but at SIP plans and control measures required to bring a nonattainment area into attainment of the 1997 annual $PM_{2.5}$ NAAQS. By contrast, redesignation to attainment primarily requires the nonattainment area to have already attained due to permanent and enforceable emission reductions, and to demonstrate that controls in place can continue to maintain the standard. Thus, even if we regard the D.C. Circuit Court's January 4, 2013 decision as calling for ''presumptive regulation'' of $NH_3$ and VOC for $PM_{2.5}$ under the attainment planning provisions of subpart 4, those provisions in and of themselves do not require additional controls of these precursors for an area that already qualifies for redesignation. Nor does EPA believe that requiring Pennsylvania to address precursors differently than it has already would result in a substantively different outcome.

Although, as EPA has emphasized, its consideration here of precursor requirements under subpart 4 is in the context of a redesignation to attainment, EPA's existing interpretation of subpart 4 requirements with respect to precursors in attainment plans for $PM_{10}$ contemplates that states may develop attainment plans that regulate only those precursors that are necessary for purposes of attainment in the area in question, *i.e.,* states may determine that only certain precursors need be regulated for attainment and control purposes.[11] Courts have upheld this approach to the requirements of subpart 4 for $PM_{10}$.[12] EPA believes that application of this approach to $PM_{2.5}$ precursors under subpart 4 is reasonable. Because the Area has already attained the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS with its current approach to regulation of $PM_{2.5}$ precursors, EPA believes that it is reasonable to conclude in the context of this redesignation that there is no need to revisit an attainment control strategy with respect to the treatment of precursors. Even if the D.C. Circuit Court's decision is construed to impose an obligation, in evaluating this redesignation request, to consider additional precursors under subpart 4, it would not affect EPA's approval here of Pennsylvania's request for redesignation of the Lancaster Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. In the context of a redesignation, Pennsylvania has shown that the Area has attained the standards. Moreover, Pennsylvania has shown, and EPA proposes to determine, that attainment of the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS in this Area is due to permanent and enforceable emission reductions on all precursors necessary to provide for continued attainment of the standards. *See* Section V.A.3 of this rulemaking action. It follows logically that no further control of additional precursors is necessary. Accordingly, EPA does not view the January 4, 2013 decision of the D.C. Circuit Court as precluding redesignation of the Area to attainment for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS at this time.

In summary, even if, prior to submitting its April 30, 2014 redesignation request submittal or subsequent to such submission and prior to December 31, 2014, Pennsylvania was required to address precursors for the Area under subpart 4 rather than under subpart 1, as interpreted in EPA's remanded 1997 $PM_{2.5}$ Implementation Rule, EPA would still conclude that the Area had met all applicable requirements for purposes of redesignation in accordance with section 107(d)(3)(E)(ii) and (v) of the CAA.

## V. EPA's Analysis of Pennsylvania's Submittal

EPA is proposing several rulemaking actions for the Lancaster Area: (1) To redesignate the Lancaster Area to attainment for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS; (2) to approve into the Pennsylvania SIP the associated maintenance plan for both the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS; and (3) to approve the 2007 comprehensive emissions inventory into the Pennsylvania SIP to satisfy the requirements of section 172(c)(3) of the CAA for the Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS, which is one of the CAA criteria for redesignation. EPA's proposed approval of the redesignation request and maintenance plan for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS are based upon EPA's determination that the Area continues to attain both standards, which EPA is proposing in this rulemaking action, and that all other redesignation criteria have been met for the Area. In addition, EPA is proposing to approve the 2017 and 2025 $PM_{2.5}$ and $NO_X$ MVEBs included in the maintenance plan for the Area for transportation conformity purposes. The following is a description of how Pennsylvania's April 30, 2014 submittal satisfies the requirements of the CAA including specifically section 107(d)(3)(E) for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS.

### *A. Redesignation Request*

#### 1. Attainment

On September 25, 2009 (74 FR 48863) and July 29, 2011 (76 FR 45424), EPA determined that the Lancaster Area

[10] The Area has reduced VOC emissions through the implementation of various control programs including VOC Reasonably Available Control Technology (RACT) regulations and various on-road and non-road motor vehicle control programs.

[11] *See, e.g.,* ''Approval and Promulgation of Implementation Plans for California—San Joaquin Valley $PM_{10}$ Nonattainment Area; Serious Area Plan for Nonattainment of the 24-Hour and Annual $PM_{10}$ Standards,'' (69 FR 30006, May 26, 2004) (approving a $PM_{10}$ attainment plan that impose controls on direct $PM_{10}$ and $NO_X$ emissions and did not impose controls on $SO_2$, VOC, or $NH_3$ emissions).

[12] *See, e.g., Assoc. of Irritated Residents* v. *EPA et al.,* 423 F.3d 989 (9th Cir. 2005).

attained the 1997 annual $PM_{2.5}$ NAAQS based on quality-assured and certified ambient air monitoring data for 2006–2008 and attained by its applicable attainment date of April 5, 2010 based on quality-assured and certified ambient air quality monitoring data for 2007–2009, respectively. In a separate rulemaking action dated March 29, 2012 (77 FR 18922), EPA determined that the Lancaster Area attained the 2006 24-hour $PM_{2.5}$ NAAQS, based on quality-assured and certified ambient air quality monitoring data for 2008–2010. The basis and effect of these determinations of attainment for both the 1997 and 2006 $PM_{2.5}$ NAAQS were discussed in the notices of the proposed (74 FR 38158 (July 31, 2009) and 77 FR 2941 (January 20, 2012), respectively) and final (74 FR 48863 and 77 FR 18922, respectively) rulemakings which determined the Area attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, respectively.

EPA has reviewed the ambient air quality $PM_{2.5}$ monitoring data in the Lancaster Area, consistent with the requirements contained in 40 CFR part 50, and recorded in EPA's Air Quality System (AQS), including quality-assured, quality-controlled, and state-certified data for the monitoring periods 2007–2009, 2008–2010, 2009–2011, 2010–2012, and 2011–2013. This data, provided in Tables 1 and 2, shows that the Area continues to attain the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS.

TABLE 1—LANCASTER AREA'S ANNUAL DESIGN VALUES FOR THE 1997 ANNUAL $PM_{2.5}$ STANDARD FOR THE 2007–2013 MONITORING PERIODS, IN μg/m³

| Monitor ID No. | 2007–2009 | 2008–2010 | 2009–2011 | 2010–2012 | 2011–2013 |
|---|---|---|---|---|---|
| 42–071–0007 | 13.8 | 12.6 | 12.0 | 12.1 | 12.0 |

TABLE 2—LANCASTER AREA'S 24-HOUR DESIGN VALUES FOR THE 2006 24-HOUR $PM_{2.5}$ STANDARD FOR THE 2007–2013 MONITORING PERIODS, IN μg/m³

| Monitor ID No. | 2007–2009 | 2008–2010 | 2009–2011 | 2010–2012 | 2011–2013 |
|---|---|---|---|---|---|
| 42–071–0007 | 35 | 33 | 31 | 31 | 31 |

EPA's review of the monitoring data from 2007 through 2013 supports EPA's previous determinations that the Area has attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, and that the Area continues to attain both standards. In addition, as discussed subsequently, with respect to the maintenance plan, Pennsylvania has committed to continue monitoring ambient $PM_{2.5}$ concentrations in accordance with 40 CFR part 58. Thus, based upon analysis of currently available data, EPA is proposing to determine that the Lancaster Area continues to attain the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS.

2. The Area Has Met All Applicable Requirements Under Section 110 and Subpart 1 of the CAA and Has a Fully Approved SIP Under Section 110(k)

In accordance with section 107(d)(3)(E)(v), the SIP revision for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS for the Lancaster Area must be fully approved under section 110(k) and all the requirements applicable to the Lancaster Area under section 110 of the CAA (general SIP requirements) and part D of Title I of the CAA (SIP requirements for nonattainment areas) must be met.

a. Section 110 General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in section 110(a)(2) include, but are not limited to, the following: (1) Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing; (2) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (3) implementation of a minor source permit program and provisions for the implementation of part C requirements (PSD); (4) provisions for the implementation of part D requirements for NSR permit programs; (5) provisions for air pollution modeling; and (6) provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) of the CAA requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision for various NAAQS, EPA has required certain states to establish programs to address transport of air pollutants in accordance with EPA's Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone (63 FR 57356, October 27, 1998), also known as the $NO_X$ SIP Call; amendments to the $NO_X$ SIP Call (64 FR 26298, May 14, 1999 and 65 FR 11222, March 2, 2000), CAIR (70 FR 25162, May 12, 2005) and CSAPR. However, section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, EPA does not believe that these requirements are applicable requirements for purposes of redesignation.

In addition, EPA believes that the other section 110(a)(2) elements not connected with nonattainment plan submissions and not linked with an area's attainment status are not applicable requirements for purposes of redesignation. The Lancaster Area will still be subject to these requirements after it is redesignated. EPA concludes that the section 110(a)(2) and part D requirements which are linked with a particular area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request, and that section 110(a)(2) elements not linked to the area's

nonattainment status are not applicable for purposes of redesignation. This approach is consistent with EPA's existing policy on applicability of conformity (*i.e.,* for redesignations) and oxygenated fuels requirement. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174, October 10, 1996), (62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida, final rulemaking (60 FR 62748, December 7, 1995). For additional discussion on this issue, see the Cincinnati, Ohio redesignation (65 FR at 37890, June 19, 2000) and the Pittsburgh-Beaver Valley, Pennsylvania redesignation (66 FR at 53099, October 19, 2001).

EPA has reviewed the Pennsylvania SIP and has concluded that it meets the general SIP requirements under section 110(a)(2) of the CAA to the extent they are applicable for purposes of redesignation. EPA has previously approved provisions of Pennsylvania's SIP addressing section 110(a)(2) requirements, including provisions addressing $PM_{2.5}$. *See* 77 FR 58955 September 25, 2012 (approving infrastructure submittals for 1997 and 2006 $PM_{2.5}$ NAAQS). These requirements are, however, statewide requirements that are not linked to the $PM_{2.5}$ nonattainment status of the Lancaster Area. Therefore, EPA believes that these SIP elements are not applicable requirements for purposes of review of the Commonwealth's $PM_{2.5}$ redesignation request.

b. Subpart 1 Requirements

Subpart 1 sets forth the basic nonattainment plan requirements applicable to $PM_{2.5}$ nonattainment areas. Under section 172, states with nonattainment areas must submit plans providing for timely attainment and must meet a variety of other requirements.

EPA's longstanding interpretation of the nonattainment planning requirements of section 172 is that once an area is attaining the NAAQS, those requirements are not ''applicable'' for purposes of section 107(d)(3)(E)(ii) and therefore need not be approved into the SIP before EPA can redesignate the area. In the 1992 General Preamble for Implementation of Title I, EPA set forth its interpretation of applicable requirements for purposes of evaluating redesignation requests when an area is attaining a standard. *See* 57 FR 13498, 13564 (April 16, 1992). EPA noted that the requirements for RFP and other measures designed to provide for attainment do not apply in evaluating redesignation requests because those nonattainment planning requirements ''have no meaning'' for an area that has already attained the standard. *Id.* This interpretation was also set forth in the 1992 Calcagni Memorandum. EPA's understanding of section 172 also forms the basis of its Clean Data Policy, which was articulated with regard to $PM_{2.5}$ in 40 CFR 51.1004(c), and suspends a state's obligation to submit most of the attainment planning requirements that would otherwise apply, including an attainment demonstration and planning SIPs to provide for RFP, RACM, and contingency measures under section 172(c)(9).[13] Courts have upheld EPA's interpretation of section 172(c)(1)'s ''reasonably available'' control measures and control technology as meaning only those controls that advance attainment, which precludes the need to require additional measures where an area is already attaining. *NRDC* v. *EPA,* 571 F.3d 1245, 1252 (D.C. Cir. 2009); *Sierra Club* v. *EPA,* 294 F.3d 155, 162 (D.C. Cir. 2002); *Sierra Club* v. *EPA,* 314 F.3d 735, 744 (5th Cir. 2002).

Therefore, because attainment has been reached for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in the Lancaster Area (*see* September 25, 2009 (74 FR 48863) and March 29, 2012 (77 FR 18922)), no additional measures are needed to provide for attainment, and section 172(c)(1) requirements for an attainment demonstration and RACM are no longer considered to be applicable for purposes of redesignation as long as the Area continues to attain both standards until redesignation. Section 172(c)(2)'s requirement that nonattainment plans contain provisions promoting reasonable further progress toward attainment is also not relevant for purposes of redesignation because EPA has determined that the Lancaster Area has monitored attainment of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. In addition, because the Lancaster Area has attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS and is no longer subject to an RFP requirement, the requirement to submit the section 172(c)(9) contingency measures is not applicable for purposes of redesignation. Section 172(c)(6) requires the SIP to contain control measures necessary to provide for attainment of the NAAQS. Because attainment has been reached, no additional measures are needed to provide for attainment.

The requirement under section 172(c)(3) of the CAA was not suspended by EPA's clean data determination for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS and is the only remaining requirement under section 172 to be considered for purposes of redesignation of the Area. Section 172(c)(3) of the CAA requires submission and approval of a comprehensive, accurate, and current inventory of actual emissions. To satisfy the 172(c)(3) requirement for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS, Pennsylvania's April 30, 2014 redesignation request and maintenance plan for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS contains a 2007 comprehensive emissions inventory. The 2007 emissions inventory was the most current accurate and comprehensive emissions inventory of $PM_{2.5}$, $NO_X$, $SO_2$, VOC, and $NH_3$ for the Area when the Area attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. Thus, as part of this rulemaking action, EPA is proposing to approve Pennsylvania's 2007 comprehensive emissions inventory for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS as satisfying the requirement of section 172(c)(3) of the CAA for both standards. Final approval of the 2007 base year emissions inventory will satisfy the emissions inventory requirement under section 172(c)(3) of the CAA for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. The 2007 comprehensive emissions inventory addresses the general source categories of point sources, area sources, on-road mobile sources, and non-road mobile sources. A summary of the 2007 comprehensive emissions inventory is shown in Table 3. For more information on EPA's analysis of the 2007 emissions inventory, *see* the TSD prepared by the EPA Region III Office of Air Monitoring and Analysis dated February 5, 2015, ''Technical Support Document (TSD) for the Redesignation Request and Maintenance Plan for the Lancaster, PA 1997 and 2006 $PM_{2.5}$ Nonattainment Area'' (Inventory TSD), available in the docket for this rulemaking action at *www.regulations.gov. See* Docket ID No. EPA–R03–OAR–2015–0050.

[13] This regulation was promulgated as part of the 1997 $PM_{2.5}$ NAAQS implementation rule that was subsequently challenged and remanded in *NRDC* v. *EPA,* 706 F.3d 428 (D.C. Cir. 2013), as discussed in Section IV.B of this rulemaking. However, the Clean Data Policy portion of the implementation rule was not at issue in that case.

TABLE 3—2007 EMISSIONS FOR THE LANCASTER AREA, IN TONS PER YEAR (TPY)

| Sector | $PM_{2.5}$ | $SO_2$ | $NO_X$ | VOC | $NH_3$ |
|---|---|---|---|---|---|
| Point | 254 | 102 | 1,147 | 2,691 | 8 |
| Area | 2,691 | 3,030 | 1,827 | 6,675 | 15,551 |
| Onroad | 480 | 102 | 13,895 | 5,529 | 207 |
| Nonroad | 290 | 148 | 3,173 | 4,627 | 3 |
| Total | 3,715 | 3,382 | 20,041 | 19,522 | 15,769 |

Section 172(c)(4) of the CAA requires the identification and quantification of allowable emissions for major new and modified stationary sources in an area, and section 172(c)(5) requires source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area. EPA has determined that, since PSD requirements will apply after redesignation, areas being redesignated need not comply with the requirement that a nonattainment NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without part D NSR. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, ''Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.'' Nevertheless, Pennsylvania currently has an approved NSR program codified in Pennsylvania's regulations at 25 Pa. Code 127.201 *et seq. See* 77 FR 41276 (July 13, 2012) (approving NSR program into the SIP). *See also* 49 FR 33127 (August 21, 1984) (approving Pennsylvania's PSD program which incorporates by reference the Federal PSD program at 40 CFR 52.21). However, Pennsylvania's PSD program will become effective in the Lancaster Area upon redesignation to attainment.

Section 172(c)(7) of the CAA requires the SIP to meet the applicable provisions of section 110(a)(2). As noted previously, EPA believes the Pennsylvania SIP meets the requirements of section 110(a)(2) that are applicable for purposes of redesignation.

Section 175A requires a state seeking redesignation to attainment to submit a SIP revision to provide for the maintenance of the NAAQS in the area ''for at least 10 years after the redesignation.'' On April 30, 2014, in conjunction with its request to redesignate the Lancaster Area to attainment status, Pennsylvania submitted a SIP revision to provide for maintenance of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in the Lancaster Area for at least 10 years after redesignation, throughout 2025. Pennsylvania is requesting that EPA approve the maintenance plan to meet the requirement of section 175A of the CAA for both NAAQS. Once approved, the maintenance plan for the Area will ensure that the SIP for Pennsylvania meets the requirements of the CAA regarding maintenance of the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS for the Area. EPA's analysis of the maintenance plan is provided in Section V.B. of this proposed rulemaking action.

Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that Federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects that are developed, funded or approved under Title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity) as well as to all other Federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with Federal conformity regulations relating to consultation, enforcement and enforceability which EPA promulgated pursuant to its authority under the CAA. EPA approved Pennsylvania's transportation conformity SIP requirements on April 29, 2009 (74 FR 19541).

EPA interprets the conformity SIP requirements as not applying for purposes of evaluating a redesignation request under CAA section 107(d) because state conformity rules are still required after redesignation, and Federal conformity rules apply where state rules have not been approved. *See Wall* v. *EPA,* 265 F. 3d 426 (6th Cir. 2001) (upholding this interpretation) and 60 FR 62748 (December 7, 1995) (discussing Tampa, Florida).

Thus, for purposes of redesignating to attainment the Lancaster Area for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS, EPA proposes that upon final approval of the 2007 comprehensive emissions inventory as proposed in this rulemaking action, Pennsylvania will meet all the applicable SIP requirements under part D of Title I of the CAA for purposes of redesignating the Area to attainment for both the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS.

c. The Lancaster Area has a Fully Approved Applicable SIP Under Section 110(k) of the CAA

Upon final approval of the 2007 comprehensive emissions inventory as proposed in this rulemaking action, EPA will have fully approved all applicable requirements of Pennsylvania's SIP for the Lancaster Area for purposes of redesignation to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS in accordance with section 110(k) of the CAA.

3. Permanent and Enforceable Reductions in Emissions

For redesignating a nonattainment area to attainment, section 107(d)(3)(E)(iii) requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP and applicable Federal air pollution control regulations and other permanent and enforceable reductions. Pennsylvania has calculated the change in emissions between 2002, a year showing nonattainment for the 1997 annual $PM_{2.5}$ NAAQS in the Lancaster Area, and 2007, one of the years for which the Lancaster Area monitored attainment for both standards.

A summary of the emissions reductions of $PM_{2.5}$, $NO_X$, $SO_2$, VOC, and $NH_3$ from 2002 to 2007 in the Lancaster Area, submitted by PADEP, is provided in Table 4. For more information on EPA's analysis of the 2007 emissions inventories, see EPA's Inventory TSD, dated February 5, 2015, available in the docket for this rulemaking action at *www.regulations.gov*.

TABLE 4—EMISSION REDUCTIONS FROM 2002 TO 2007 IN THE LANCASTER AREA (TPY)

| | Sector | 2002 | 2007 | Net reduction 2002–2007 | Percent reduction 2002–2007 |
|---|---|---|---|---|---|
| $PM_{2.5}$ | Point | 380 | 254 | 127 | 33 |
| | Area | 3,612 | 2,691 | 922 | 26 |
| | On-road | 541 | 480 | 60 | 11 |
| | Non-road | 322 | 290 | −2 | −1 |
| | Total | 4,856 | 3,715 | 1,140 | 23 |
| $NO_X$ | Point | 1,368 | 1,147 | 221 | 16 |
| | Area | 1,739 | 1,827 | −87 | −5 |
| | On-road | 17,466 | 13,895 | 3,572 | 20 |
| | Non-road | 4,001 | 3,173 | 828 | 21 |
| | Total | 24,575 | 20,041 | 4,534 | 18 |
| $SO_2$ | Point | 498 | 102 | 395 | 79 |
| | Area | 2,735 | 3,030 | −295 | −11 |
| | On-road | 362 | 102 | 260 | 72 |
| | Non-road | 295 | 148 | 147 | 50 |
| | Total | 3,890 | 3,382 | 508 | 13 |
| VOC | Point | 3,188 | 2,691 | 497 | 16 |
| | Area | 9,887 | 6,675 | 3,212 | 32 |
| | On-road | 6,481 | 5,529 | 953 | 15 |
| | Non-road | 5,009 | 4,627 | 382 | 8 |
| | Total | 24,566 | 19,522 | 5,044 | 21 |
| $NH_3$ | Point | 12 | 8 | 4 | 33 |
| | Area | 15,994 | 15,551 | 444 | 3 |
| | On-road | 222 | 207 | 15 | 7 |
| | Non-road | 3 | 3 | 0 | 0 |
| | Total | 16,231 | 15,769 | 462 | 3 |

The reduction in emissions and the corresponding improvement in air quality from 2002 to 2007 for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, respectively, in the Lancaster Area can be attributed to a number of regulatory control measures that have been implemented in the Area and contributing areas in recent years.

a. Federal Measures Implemented

Reductions in $PM_{2.5}$ precursor emissions have occurred statewide and in upwind states as a result of Federal emission control measures, with additional emission reductions expected to occur in the future.

Control of $NO_X$ and $SO_2$

$PM_{2.5}$ concentrations in the Lancaster Area are impacted by the transport of sulfates and nitrates, and the Area's air quality is strongly affected by regulation of $SO_2$ and $NO_X$ emissions from power plants.

*$NO_X$ SIP Call*—On October 27, 1998 (63 FR 57356), EPA issued the $NO_X$ SIP Call requiring the District of Columbia and 22 states to reduce emissions of $NO_X$, a precursor to ozone pollution.[14] Affected states were required to comply with Phase I of the SIP Call beginning in 2004 and Phase II beginning in 2007. Emission reductions resulting from regulations developed in response to the $NO_X$ SIP Call are permanent and enforceable. By imposing an emissions cap regionally, the $NO_X$ SIP Call reduced $NO_X$ emissions from large EGUs and large non-EGUs such as industrial boilers, internal combustion engines, and cement kilns. In response to the $NO_X$ SIP Call, Pennsylvania adopted its $NO_X$ Budget Trading Program regulations for EGUs and large industrial boilers, with emission reductions starting in May 2003. Pennsylvania's $NO_X$ Budget Trading Program regulation was approved into the Pennsylvania SIP on August 21, 2001 (66 FR 43795). To meet other requirements of the $NO_X$ SIP Call, Pennsylvania adopted $NO_X$ control regulations for cement plants and internal combustion engines, with emission reductions starting in May 2005. These regulations were approved into the Pennsylvania SIP on September 29, 2006 (71 FR 57428).

*CAIR*—As previously noted, CAIR (70 FR 25162, May 12, 2005) created regional cap-and-trade programs to reduce $SO_2$ and $NO_X$ emissions in 27 eastern states, including Pennsylvania. EPA approved the Commonwealth's CAIR regulation, codified in 25 Pa. Code Chapter 145, Subchapter D, into the Pennsylvania SIP on December 10, 2009 (74 FR 65446). In 2009, the CAIR ozone season $NO_X$ trading program superseded the $NO_X$ Budget Trading Program, although the emission reduction obligations of the $NO_X$ SIP Call were not rescinded. *See* 40 CFR 51.121(r) and 51.123(aa). EPA promulgated CSAPR to replace CAIR as an emission trading program for EGUs. As discussed previously, pursuant to the D.C. Circuit Court's October 23, 2014 Order, the stay of CSAPR has been lifted and implementation of CSAPR commenced in January 2015. EPA expects that the implementation of CSAPR will preserve the reductions achieved by CAIR and

[14] Although the $NO_X$ SIP Call was issued in order to address ozone pollution, reductions of $NO_X$ as a result of that program have also impacted $PM_{2.5}$ pollution, for which $NO_X$ is also a precursor emission.

result in additional $SO_2$ and $NO_X$ emission reductions throughout the maintenance period.

Tier 2 Emission Standards for Vehicles and Gasoline Sulfur Standards

These emission control requirements result in lower $NO_X$ emissions from new cars and light duty trucks, including sport utility vehicles. The Federal rules were phased in between 2004 and 2009. EPA estimated that, after phasing in the new requirements, the following vehicle $NO_X$ emission reductions will have occurred nationwide: Passenger cars (light duty vehicles) (77 percent); light duty trucks, minivans, and sports utility vehicles (86 percent); and larger sports utility vehicles, vans, and heavier trucks (69 to 95 percent). Some of the emissions reductions resulting from new vehicle standards occurred during the 2008–2010 attainment period; however, additional reductions will continue to occur throughout the maintenance period as new vehicles replace older vehicles. EPA expects fleet wide average emissions to decline by similar percentages as new vehicles replace older vehicles.

Heavy-Duty Diesel Engine Rule

EPA issued the Heavy-Duty Diesel Engine Rule in July 2000. This rule included standards limiting the sulfur content of diesel fuel, which went into effect in 2004. A second phase took effect in 2007 which reduced $PM_{2.5}$ emissions from heavy-duty highway engines and further reduced the highway diesel fuel sulfur content to 15 parts per million (ppm). Standards for gasoline engines were phased in starting in 2008. The total program is estimated to achieve a 90 percent reduction in direct $PM_{2.5}$ emissions and a 95 percent reduction in $NO_X$ emissions for new engines using low sulfur diesel fuel.

Nonroad Diesel Rule

On June 29, 2004 (69 FR 38958), EPA promulgated the Nonroad Diesel Rule for large nonroad diesel engines, such as those used in construction, agriculture, and mining, to be phased in between 2008 and 2014. The rule phased in requirements for reducing the sulfur content of diesel used in nonroad diesel engines. The reduction in sulfur content prevents damage to the more advanced emission control systems needed to meet the engine standards. It will also reduce fine particulate emissions from diesel engines. The combined engine standards and the sulfur in fuel reductions will reduce $NO_X$ and PM emissions from large nonroad engines by over 90 percent, compared to current nonroad engines using higher sulfur content diesel.

Nonroad Large Spark-Ignition Engine and Recreational Engine Standards

In November 2002, EPA promulgated emission standards for groups of previously unregulated nonroad engines. These engines include large spark-ignition engines such as those used in forklifts and airport ground-service equipment; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines. Emission standards from large spark-ignition engines were implemented in two tiers, with Tier 1 starting in 2004 and Tier 2 in 2007. Recreational vehicle emission standards are being phased in from 2006 through 2012. Marine Diesel engine standards were phased in from 2006 through 2009. With full implementation of all of the nonroad spark-ignition engine and recreational engine standards, an overall 80 percent reduction in $NO_X$ is expected by 2020. Some of these emission reductions occurred by the 2002–2007 attainment period and additional emission reductions will occur during the maintenance period as the fleet turns over.

Federal Standards for Hazardous Air Pollutants

As required by the CAA, EPA developed Maximum Available Control Technology (MACT) Standards to regulate emissions of hazardous air pollutants from a published list of industrial sources referred to as ''source categories.'' The MACT standards have been adopted and incorporated by reference in Section 6.6 of Pennsylvania's Air Pollution Control Act and implementing regulations in 25 Pa. Code § 127.35 and are also included in Federally enforceable permits issued by PADEP for affected sources. The Industrial/Commercial/Institutional (ICI) Boiler MACT standards (69 FR 55217, September 13, 2004, and 76 FR 15554, February 21, 2011) are estimated to reduce emissions of PM, $SO_2$, and VOCs from major source boilers and process heaters nationwide. Also, the Reciprocating Internal Combustion Engines (RICE) MACT will reduce $NO_X$ and PM emissions from engines located at facilities such as pipeline compressor stations, chemical and manufacturing plants, and power plants.

b. State Measures

Heavy-Duty Diesel Emissions Control Program

In 2002, Pennsylvania adopted the Heavy-Duty Diesel Emissions Control Program for model years starting in May 2004. The program incorporates California standards by reference and required model year 2005 and beyond heavy-duty diesel highway engines to be certified to the California standards, which were more stringent than the Federal standards for model years 2005 and 2006. After model year 2006, Pennsylvania required implementation of the Federal standards that applied to model years 2007 and beyond, discussed in the Federal measures section of this proposed rulemaking action. This program reduced emissions of $NO_X$ statewide.

Vehicle Emission Inspection/Maintenance (I/M) Program

Pennsylvania's Vehicle Emission I/M program was expanded to the Lancaster area in early 2004 and applies to model year 1975 and newer gasoline-powered vehicles that are 9,000 pounds and under. The program, approved into the Pennsylvania SIP on October 6, 2005 (70 FR 58313), consists of annual on-board diagnostics and gas cap test for model year 1996 vehicles and newer, and an annual visual inspection of pollution control devices and gas cap test for model year 1995 vehicles and older. This program reduces emissions of $NO_X$ from affected vehicles.

Consumer Products Regulation

Pennsylvania regulation ''Chapter 130, Subchapter B. Consumer Products'' established, effective January 1, 2005, VOC emission limits for numerous categories of consumer products, and applies statewide to any person who sells, supplies, offers for sale, or manufactures such consumer products on or after January 1, 2005 for use in Pennsylvania. It was approved into the Pennsylvania SIP on December 8, 2004 (69 FR 70895).

Adhesives, Sealants, Primers and Solvents Regulation

Pennsylvania adopted a regulation in 2010 to control VOC emissions from adhesives, sealants, primers and solvents. This regulation was approved into the Pennsylvania SIP on September 26, 2012 (77 FR 59090).

Based on the information summarized above, Pennsylvania has adequately demonstrated that the improvements in air quality in the Lancaster Area are due to permanent and enforceable emissions reductions. The reductions result from

Federal and State requirements and regulation of precursors within Pennsylvania that affect the Lancaster Area.

*B. Maintenance Plan*

On April 30, 2014, PADEP submitted a combined maintenance plan for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, as required by section 175A of the CAA. EPA's analysis for proposing approval of the maintenance plan is provided in this section.

1. Attainment Emissions Inventories

An attainment inventory is comprised of the emissions during the time period associated with the monitoring data showing attainment. PADEP determined that the appropriate attainment inventory year for the maintenance plan for the 1997 annual $PM_{2.5}$ NAAQS is 2007, one of the years in the periods during which the Lancaster Area monitored attainment of the 1997 annual $PM_{2.5}$ NAAQS. PADEP determined that the appropriate attainment inventory year for the maintenance plan for the 2006 24-hour $PM_{2.5}$ NAAQS is 2007, one of the years in the periods during which the Lancaster Area monitored attainment of the 2006 24-hour $PM_{2.5}$ NAAQS. The 2007 inventory included in the maintenance plan contains primary $PM_{2.5}$ emissions (including condensables), $SO_2$, $NO_X$, VOC, and $NH_3$.

In its redesignation request and maintenance plan for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, PADEP described the methods used for developing its 2007 inventory. EPA reviewed the procedures used to develop the inventory and found them to be reasonable. EPA has reviewed the documentation provided by PADEP and found the 2007 emissions inventory submitted with the maintenance plan to be approvable. For more information on EPA's analysis of the 2007 emissions inventory, *see* EPA's Inventory TSD, dated February 5, 2015, available in the docket for this rulemaking action at *www.regulations.gov*.

2. Maintenance Demonstration

Section 175A requires a state seeking redesignation to attainment to submit a SIP revision to provide for the maintenance of the NAAQS in the area ''for at least 10 years after the redesignation.'' EPA has interpreted this as a showing of maintenance ''for a period of ten years following redesignation.'' The Federal and State measures described in Section V.A.3 of this proposed rulemaking action demonstrate that the reductions in emissions from point, area, and mobile sources in the Area has occurred and will continue to occur through 2025. In addition, the following State and Federal regulations and programs ensure the continuing decline of $SO_2$, $NO_X$, $PM_{2.5}$, and VOC emissions in the Area during the maintenance period and beyond:

Non-EGUs Previously Covered Under the $NO_X$ SIP Call

Pennsylvania established $NO_X$ emission limits for the large industrial boilers that were previously subject to the $NO_X$ SIP Call, but were not subject to CAIR. For these units, Pennsylvania established an allowable ozone season $NO_X$ limit based on the unit's previous ozone season's heat input. A combined $NO_X$ ozone season emissions cap of 3,418 tons applies for all of these units.

CSAPR (August 8, 2011, 76 FR 48208)

EPA promulgated CSAPR to replace CAIR as an emission trading program for EGUs. As discussed previously, implementation of CSAPR commenced in January 2015. EPA expects that the implementation of CSAPR will preserve the reductions achieved by CAIR and result in additional $SO_2$ and $NO_X$ emission reductions throughout the maintenance period.

Regulation of Cement Kilns

On July 19, 2011 (76 FR 52558), EPA approved amendments to 25 Pa. Code Chapter 145 Subchapter C to further reduce $NO_X$ emissions from cement kilns. The amendments established $NO_X$ emission rate limits for long wet kilns, long dry kilns, and preheater and precalciner kilns that are lower by 35 percent to 63 percent from the previous limit of 6 pounds of $NO_X$ per ton of clinker that applied to all kilns. The amendments were effective on April 15, 2011.

Stationary Source Regulations

Pennsylvania regulation 25 Pa. Code Chapter 130, Subchapter D for Adhesives, Sealers, Primers, and Solvents was approved into the Pennsylvania SIP on September 26, 2012 (77 FR 59090). The regulation established VOC content limits for various categories of adhesives, sealants, primers, and solvent, and became applicable on January 1, 2012.

Amendments to Pennsylvania regulation 25 Pa. Code Chapter 130, Subchapter B established, effective January 1, 2009, new or more stringent VOC standards for consumer products. The amendments were approved into the Pennsylvania SIP on October 18, 2010 (75 FR 63717).

Pennsylvania's Clean Vehicle Program

The Pennsylvania Clean Vehicles Program (formerly, New Motor Vehicle Control Program) incorporates by reference the California Low Emission Vehicle program (CA LEVII), although it allowed automakers to comply with the NLEV program as an alternative to this program until Model Year (MY) 2006. The Clean Vehicles Program, codified in 25 Pa. Code Chapter 126, Subchapter D, was modified to require CA LEVII to apply to MY 2008 and beyond, and was approved into the Pennsylvania SIP on January 24, 2012 (77 FR 3386). The Clean Vehicles Program incorporates by reference the emission control standards of CA LEVII, which, among other requirements, reduces emissions of $NO_X$ by requiring that passenger car emission standards and fleet average emission standards also apply to light duty vehicles. Model year 2008 and newer passenger cars and light duty trucks are required to be certified for emissions by the California Air Resource Board (CARB), in order to be sold, leased, offered for sale or lease, imported, delivered, purchased, rented, acquired, received, titled or registered in Pennsylvania. In addition, manufacturers are required to demonstrate that the California fleet average standard is met based on the number of new light-duty vehicles delivered for sale in the Commonwealth. The Commonwealth's submittal for the January 24, 2012 rulemaking projected that, by 2025, the program will achieve approximately 75 tons more $NO_X$ reductions than Tier II for the Lancaster Area.

Two Pennsylvania regulations—the Diesel-Powered Motor Vehicle Idling Act (August 1, 2011, 76 FR 45705) and the Outdoor Wood-Fired Boiler regulation (September 20, 2011, 76 FR 58114)—were not included in the projection inventories, but may also assist in maintaining the standard. Also, the Tier 3 Motor Vehicle Emission and Fuel Standards (79 FR 23414, April 29, 2014) establishes more stringent vehicle emissions standards and will reduce the sulfur content of gasoline beginning in 2017. The fuel standard will achieve $NO_X$ reductions by further increasing the effectiveness of vehicle emission controls for both existing and new vehicles.

The State and Federal regulations and programs described above ensure the continuing decline of $SO_2$, $NO_X$, $PM_{2.5}$, and VOC emissions in the Area during the maintenance period and beyond. A summary of the projected reductions from these measures from 2007 to 2025 is shown in Table 5. Table 5

incorporates the expected emissions from potential emissions increases from Emission Reduction Credits (ERCs), which are also included in Tables 6a–6e.

TABLE 5—EMISSION REDUCTIONS (TONS) FROM 2007 TO 2025 DUE TO CONTROL MEASURES

| | $PM_{2.5}$ | $NO_X$ | $SO_2$ | VOC | $NH_3$ |
|---|---|---|---|---|---|
| Point | −18 | −238 | −18 | −355 | −3 |
| Area | 81 | 122 | 1,264 | 249 | −2,821 |
| On-Road | 295 | 9,447 | 63 | 3,661 | 63 |
| Non-Road | 158 | 1,862 | 142 | 2,388 | −1 |
| Totals | 516 | 11,194 | 1,451 | 5,942 | −2,762 |

Where the emissions inventory method of showing maintenance is used, its purpose is to show that emissions during the maintenance period will not increase over the attainment year inventory. *See* 1992 Calcagni Memorandum, pages 9–10. For a demonstration of maintenance, emissions inventories are required to be projected to future dates to assess the influence of future growth and controls; however, the demonstration need not be based on modeling. *See Wall* v. *EPA, supra; Sierra Club* v. *EPA, supra. See also* 66 FR 53099–53100 and 68 FR 25430–32. PADEP uses projection inventories to show that the Lancaster Area will remain in attainment and developed projection inventories for an interim year of 2017 and a maintenance plan end year of 2025 to show that future emissions of $NO_X$, $SO_2$, $PM_{2.5}$, and VOC will remain at or below the attainment year 2007 attainment-level emissions levels, for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, respectively, throughout the Lancaster Area through the year 2025. Although emissions of $NH_3$ are projected to increase from 2007 to 2017 and from 2007 to 2025, the increase will not affect the Area's ability to maintain the standard because such increases are more than compensated by the significant reductions of the other precursors that are projected during the maintenance period.

EPA has reviewed the documentation provided by PADEP for developing annual 2017 and 2025 emissions inventories for the Lancaster portion of the Area. *See* Appendix C–2 and C–3 of Pennsylvania's submittal. EPA has determined that the 2017 and 2025 projected emissions inventories provided by PADEP are approvable. For more information on EPA's analysis of the emissions inventories, *see* EPA's Inventory TSD, dated February 5, 2015 available in the docket for this rulemaking action at *www.regulations.gov.*

Tables 6a through 6e provide a summary of the inventories in tpy for the 2007 attainment year, as compared to projected inventories for the 2017 interim year and the 2025 maintenance plan end year for the Area.

TABLE 6A—COMPARISON OF 2007, 2017, AND 2025 EMISSIONS OF $PM_{2.5}$ FOR THE LANCASTER AREA

| $PM_{2.5}$ | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sector | 2007 | 2017 | 2025 | 2007–2017 | | 2007–2025 | |
| | | | | Reduction | Percent reduction | Reduction | Percent reduction |
| Point | 254 | 267 | 272 | −13 | −5 | −18 | −7 |
| Area | 2,691 | 2,649 | 2,610 | 42 | 2 | 81 | 3 |
| On-Road | 480 | 249 | 185 | 231 | 48 | 295 | 61 |
| Non-Road | 290 | 182 | 132 | 108 | 37 | 158 | 54 |
| ERC | | 0 | 0 | | | | |
| Total | 3,715 | 3,348 | 3,200 | 368 | 10 | 516 | 14 |

TABLE 6B—COMPARISON OF 2007, 2017, AND 2025 EMISSIONS OF $NO_X$ FOR THE LANCASTER AREA

| $NO_X$ | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sector | 2007 | 2017 | 2025 | 2007–2017 | | 2007–2025 | |
| | | | | Reduction | Percent reduction | Reduction | Percent reduction |
| Point | 1,147 | 1,314 | 1,383 | −167 | −15 | −236 | −21 |
| Area | 1,827 | 1,702 | 1,704 | 125 | 7 | 123 | 7 |
| On-Road | 13,895 | 6,916 | 4,447 | 6,979 | 50 | 9,448 | 68 |
| Non-Road | 3,173 | 1,775 | 1,310 | 1,398 | 44 | 1,863 | 59 |
| ERC | | 2 | 2 | −2 | | −2 | |
| Total | 20,041 | 11,710 | 8,847 | 8,333 | 42 | 11,196 | 56 |

TABLE 6C—COMPARISON OF 2007, 2017, AND 2025 EMISSIONS OF $SO_2$ FOR THE LANCASTER AREA

| $SO_2$ | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sector | 2007 | 2017 | 2025 | 2007–2017 | | 2007–2025 | |
| | | | | Reduction | Percent reduction | Reduction | Percent reduction |
| Point | 102 | 115 | 120 | −13 | −13 | −18 | −18 |
| Area | 3,030 | 2,449 | 1,766 | 581 | 19 | 1,264 | 42 |
| On-Road | 102 | 37 | 39 | 65 | 64 | 63 | 62 |
| Non-Road | 148 | 5 | 5 | 143 | 97 | 143 | 97 |
| ERC | | 0 | 0 | | | | |
| Total | 3,382 | 2,605 | 1,930 | 776 | 23 | 1,452 | 43 |

TABLE 6D—COMPARISON OF 2007, 2017, AND 2025 EMISSIONS OF VOC FOR THE LANCASTER AREA

| VOC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sector | 2007 | 2017 | 2025 | 2007–2017 | | 2007–2025 | |
| | | | | Reduction | Percent reduction | Reduction | Percent reduction |
| Point | 2,691 | 2,808 | 2,874 | −117 | −4 | −183 | −7 |
| Area | 6,675 | 6,459 | 6,426 | 216 | 3 | 249 | 4 |
| On-Road | 5,529 | 2,965 | 1,868 | 2,564 | 46 | 3,661 | 66 |
| Non-Road | 4,627 | 2,753 | 2,240 | 1,874 | 41 | 2,387 | 52 |
| ERC | | 172 | 172 | | | | |
| Total | 19,522 | 15,157 | 13,580 | 4,537 | 23 | 6,114 | 31 |

TABLE 6E—COMPARISON OF 2007, 2017, AND 2025 EMISSIONS OF $NH_3$ FOR THE LANCASTER AREA

| $NH_3$ | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sector | 2007 | 2017 | 2025 | 2007–2017 | | 2007–2025 | |
| | | | | Reduction | Percent reduction | Reduction | Percent reduction |
| Point | 8 | 10 | 11 | −2 | −25 | −3 | −38 |
| Area | 15,551 | 17,152 | 18,372 | −1,601 | −10 | −2,821 | −18 |
| On-Road | 207 | 148 | 144 | 59 | 29 | 63 | 30 |
| Non-Road | 3 | 4 | 4 | −1 | −33 | −1 | −33 |
| ERC | | 0 | 0 | | | | |
| Total | 15,769 | 17,314 | 18,531 | −1,545 | −10 | −2,762 | −18 |

As shown in Tables 6a–6b, the projected levels for $PM_{2.5}$, $NO_X$, $SO_2$, and VOC are under the 2007 attainment levels for each of these pollutants. While the emissions of $NH_3$ are projected to be higher than the 2007 inventory for this pollutant for both the interim year and the end-year, the decreases in the other precursors, particularly the significant reductions in $NO_X$, more than compensate for the increase, therefore, the increase in $NH_3$ is not considered to affect the Area's ability to maintain the NAAQS. The projected emissions inventories show that the Area will continue to maintain the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS during the 10 year maintenance period. Moreover, the modeling analysis conducted for the Regulatory Impact Analysis (RIA) for the 2012 $PM_{2.5}$ NAAQS indicates that the annual $PM_{2.5}$ design value for this Area is expected to continue to decline through 2020. Given the significant decrease in overall precursor emissions projected through 2025, it is reasonable to conclude that monitored $PM_{2.5}$ levels in this area will also continue to decrease through 2025. Pennsylvania has adequately demonstrated that the Area will continue to maintain the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS.

3. Monitoring Network

Pennsylvania's maintenance plan includes a commitment by PADEP to continue to operate its EPA-approved monitoring network, as necessary to demonstrate ongoing compliance with the NAAQS. Pennsylvania currently operates a $PM_{2.5}$ monitor in the Lancaster Area. In its April 30, 2014 submittal, Pennsylvania stated that it will consult with EPA prior to making any necessary changes to the network and will continue to operate the monitoring network in accordance with the requirements of 40 CFR part 58.

4. Verification of Continued Attainment

To provide for tracking of the emission levels in the Area, PADEP will: (a) Evaluate annually the vehicle miles travelled (VMT) data and the annual emissions reported from stationary sources to compare them with the assumptions used in the maintenance plan; and (b) evaluate the periodic emissions inventory for all $PM_{2.5}$ precursors prepared every three years in accordance with EPA's Air

Emissions Reporting Requirements (AERR) to determine whether there is an exceedance of more than ten percent over the 2007 inventories. Also, as noted in the previous subsection, PADEP will continue to operate its monitoring system in accordance with 40 CFR 58 and remains obligated to quality-assure monitoring data and enter all data into the AQS in accordance with federal requirements. PADEP will use this data in considering whether additional control measures are needed to assure continuing attainment in the Area.

5. Contingency Measures

The contingency plan provisions are designed to promptly correct any violation of the 1997 annual and/or the 2006 24-hour $PM_{2.5}$ NAAQS that occurs in the Lancaster Area after redesignation. Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to ensure that a state will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the events that would ''trigger'' the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the state would adopt and implement the measure(s).

Pennsylvania's maintenance plan describes the procedures for the adoption and implementation of contingency measures to reduce emissions should a violation occur. Pennsylvania's contingency measures include a first level response and a second level response. A first level response is triggered when the annual mean $PM_{2.5}$ concentration exceeds 15.5 $\mu g/m^3$ in a single calendar year within the Area, when the 98th percentile 24-hour $PM_{2.5}$ concentration exceeds 35.0 $\mu g/m^3$, or when the periodic emissions inventory for the Area exceed the attainment year inventory (2007) by more than ten percent. The first level response will consist of a study to determine if the emissions trends show increasing concentrations of $PM_{2.5}$, and whether this trend is likely to continue. If it is determined through the study that action is necessary to reverse a trend of emissions increases, Pennsylvania will, as expeditiously as possible, implement necessary and appropriate control measures to reverse the trend.

A second level response will be prompted if the two-year average of the annual mean concentration exceeds 15.0 $\mu g/m^3$ or if the 98th percentile 24-hour $PM_{2.5}$ concentration exceeds 35.0 $\mu g/m^3$within the Area. This would trigger an evaluation of the conditions causing the exceedance, whether additional emission control measures should be implemented to prevent a violation of the standard, and analysis of potential measures that could be implemented to prevent a violation. Pennsylvania would then begin its adoption process to implement the measures as expeditiously as practicable. If a violation of the $PM_{2.5}$ NAAQS occurs, PADEP will propose and adopt necessary additional control measures in accordance with the implementation schedule in the maintenance plan.

Pennsylvania's candidate contingency measures include the following: (1) A regulation based on the Ozone Transport Commission (OTC) Model Rule to update requirements for consumer products; (2) a regulation based on the Control Techniques Guidelines (CTG) for industrial cleaning solvents; (3) voluntary diesel projects such as diesel retrofit for public or private local onroad or offroad fleets, idling reduction technology for Class 2 yard locomotives, and idling reduction technologies or strategies for truck stops, warehouses, and other freight-handling facilities; (4) promotion of accelerated turnover of lawn and garden equipment, focusing on commercial equipment; and (5) promotion of alternative fuels for fleets, home heating and agricultural use. Pennsylvania's rulemaking process and schedule for adoption and implementation of any necessary contingency measure is shown in the SIP submittals as being 18 months from PADEP's approval to initiate rulemaking. For all of the reasons discussed in this section, EPA is proposing to approve Pennsylvania's 1997 annual and 2006 24-hour $PM_{2.5}$ maintenance plan for the Lancaster Area as meeting the requirements of section 175A of the CAA.

*C. Motor Vehicle Emissions Budgets*

Section 176(c) of the CAA requires Federal actions in nonattainment and maintenance areas to ''conform to'' the goals of SIPs. This means that such actions will not cause or contribute to violations of a NAAQS, worsen the severity of an existing violation, or delay timely attainment of any NAAQS or any interim milestone. Actions involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval are subject to the transportation conformity rule (40 CFR part 93, subpart A). Under this rule, metropolitan planning organizations (MPOs) in nonattainment and maintenance areas coordinate with state air quality and transportation agencies, EPA, and the FHWA and FTA to demonstrate that their long range transportation plans and transportation improvement programs (TIP) conform to applicable SIPs. This is typically determined by showing that estimated emissions from existing and planned highway and transit systems are less than or equal to the MVEBs contained in the SIP.

On April 30, 2014, Pennsylvania submitted SIP revisions that contain the 2017 and 2025 $PM_{2.5}$ and $NO_X$ onroad mobile source budgets for Lancaster County. Pennsylvania did not provide emission budgets for $SO_2$, VOC, and $NH_3$ because it concluded, consistent with the presumptions regarding these precursors in the Transportation Conformity Rule at 40 CFR 93.102(b)(2)(v), which predated and were not disturbed by the litigation on the 1997 $PM_{2.5}$ Implementation Rule, that emissions of these precursors from motor vehicles are not significant contributors to the Area's $PM_{2.5}$ air quality problem. EPA issued conformity regulations to implement the 1997 annual $PM_{2.5}$ NAAQS in July 2004 and May 2005 (69 FR 40004, July 1, 2004 and 70 FR 24280, May 6, 2005). That decision does not affect EPA's proposed approval of the MVEBs for the Area. The MVEBs are presented in Table 7.

TABLE 7—MVEBS FOR THE LANCASTER AREA FOR THE 1997 $PM_{2.5}$ AND 2006 24-HOUR NAAQS, IN TPY

| Year | $PM_{2.5}$ | $NO_X$ |
|---|---|---|
| 2017 ..... | 249 | 6,916 |
| 2025 ..... | 185 | 4,447 |

EPA's substantive criteria for determining adequacy of MVEBs are set out in 40 CFR 93.118(e)(4). Additionally, to approve the MVEBs, EPA must complete a thorough review of the SIP, in this case the $PM_{2.5}$ maintenance plan, and conclude that with the projected level of motor vehicle and all other emissions, the SIPs will achieve its overall purpose, in this case providing for maintenance of the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. EPA's process for determining adequacy of a MVEB consists of three basic steps: (1) Providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEB during a public comment period; and (3) EPA taking action on the MVEB.

In this proposed rulemaking action, EPA is also initiating the process for

determining whether or not the MVEBs are adequate for transportation conformity purposes. The publication of this proposed rulemaking action starts a 30-day public comment period on the adequacy of the submitted MVEBs. This comment period is concurrent with the comment period on this proposed rulemaking action and comments should be submitted to the docket for this rulemaking. EPA may choose to make its determination on the adequacy of the budgets either in the final rulemaking on this maintenance plan and redesignation request or by informing Pennsylvania of the determination in writing, publishing a notice in the **Federal Register** and posting a notice on EPA's adequacy Web page (*http://www.epa.gov/otaq/stateresources/transconf/adequacy.htm*).[15]

EPA has reviewed the MVEBs and finds that the submitted MVEBs are consistent with the maintenance plan and meet the criteria for adequacy and approval in 40 CFR part 93, subpart A. Therefore, EPA is proposing to approve the 2017 and 2025 $PM_{2.5}$ and $NO_X$ MVEBs for Lancaster County for transportation conformity purposes. Additional information pertaining to the review of the MVEBs can be found in the TSD dated February 25, 2015, ''Adequacy Findings for the Motor Vehicle Emissions Budgets in the Maintenance Plan for the Lancaster 1997 and 2006 $PM_{2.5}$ NAAQS Nonattainment Areas,'' available on line at *www.regulations.gov,* Docket ID No. EPA–R03–OAR–2015–0050.

## VI. Proposed Actions

EPA is proposing to approve Pennsylvania's request to redesignate the Lancaster Area from nonattainment to attainment for the 1997 annual and the 2006 24-hour $PM_{2.5}$ NAAQS. EPA has evaluated Pennsylvania's redesignation request and determined that the Area meets the redesignation criteria set forth in section 107(d)(3)(E) of the CAA. The monitoring data demonstrates that the Lancaster Area attained the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, as determined by EPA in a prior rulemaking actions and, for reasons discussed herein, that it will continue to attain both NAAQS. Final approval of this redesignation request would change the designation of the Lancaster Area from nonattainment to attainment for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS. EPA is also proposing to approve the associated maintenance plan for the Lancaster Area as a revision to the Pennsylvania SIP for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS because it meets the requirements of section 175A of the CAA as described previously in this proposed rulemaking. In addition, EPA is proposing to approve the 2007 emissions inventory as meeting the requirement of section 172(c)(3) of the CAA for both NAAQS. Furthermore, EPA is proposing to approve the 2017 and 2025 $PM_{2.5}$ and $NO_X$ MVEBs for Lancaster County for transportation conformity purposes. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

## VII. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this action proposing to approve Pennsylvania's redesignation request, maintenance plan, 2007 emissions inventory for the 1997 annual and 2006 24-hour $PM_{2.5}$ NAAQS, and MVEBs for transportation conformity purposes for the Lancaster Area for both NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

## List of Subjects

*40 CFR Part 52*

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

*40 CFR Part 81*

Air pollution control, National parks, Wilderness areas.

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

Dated: April 20, 2015.

**William C. Early,**

*Acting Regional Administrator, Region III.*

[FR Doc. 2015–10049 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

[15] For additional information on the adequacy process, please refer to 40 CFR 93.118(f) and the discussion of the adequacy process in the preamble to the 2004 final transportation conformity rule. *See* 69 FR at 40039–40043.

# Notices

Federal Register

Vol. 80, No. 84

Friday, May 1, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

**[Docket No. APHIS–2015–0013]**

### Notice of Request for Extension of Approval of an Information Collection; Domestic Quarantine Notices

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Extension of approval of an information collection; comment request.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the domestic quarantine regulations to prevent the spread of plant pests and diseases within the United States.

**DATES:** We will consider all comments that we receive on or before June 30, 2015.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docket Detail;D=APHIS-2015-0013.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0013, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0013* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** For information on the domestic quarantine regulations to prevent the spread of plant pests and diseases, contact Ms. Lynn Evans-Goldner, National Policy Manager, PHP, Plant Protection and Quarantine, APHIS, 4700 River Road, Unit 160, Riverdale, MD 20737; (301) 851–2286. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**SUPPLEMENTARY INFORMATION:**

*Title:* Domestic Quarantine Notices.

*OMB Control Number:* 0579–0088.

*Type of Request:* Extension of approval of an information collection.

*Abstract:* As authorized by the Plant Protection Act (PPA, 7 U.S. C. 7701 *et seq.*), the Secretary of Agriculture may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, means of conveyance, or other article to prevent a plant pest or noxious weed from being introduced into or disseminated within the United States. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, which administers regulations to implement the PPA.

APHIS regulations in 7 CFR part 301, ''Domestic Quarantine Notices,'' prohibit or restrict the interstate movement of certain articles from infested areas to noninfested areas to prevent the spread of plant pests. Federal and State quarantines are necessary to regulate the movement of articles from infested areas to noninfested areas. For example, if an area in the United States has been placed under quarantine due to the Asian longhorned beetle, then certain plant products (regulated articles) that are susceptible to the Asian longhorned beetle can be moved from the quarantined area only under certain conditions (*i.e.,* after inspection and issuance of a certificate or limited permit). These measures help prevent the Asian longhorned beetle from spreading from the quarantined area to noninfested areas of the United States.

Administering these regulations requires APHIS to collect information from a variety of individuals who are involved in growing, packing, handling, and transporting plants and plant products. The information serves as supporting documentation required for the issuance of forms and documents that authorize the movement of regulated plants and plant products and is vital to help prevent the spread of injurious plant pests within the United States. Collecting this information requires us to use a number of forms and documents, including certificates, limited permits, transit permits, and outdoor household article documents.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

*Estimate of burden:* The public reporting burden for this collection of information is estimated to average 0.31 hours per response.

*Respondents:* State plant regulatory officials, State cooperators, and individuals involved in growing, packing, handling, and transporting plants and plant products.

*Estimated annual number of respondents:* 27,464.

*Estimated annual number of responses per respondent:* 60.

*Estimated annual number of responses:* 1,640,893.

*Estimated total annual burden on respondents:* 512,491 hours. (Due to averaging, the total annual burden hours

may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 27th day of April 2015.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015–10194 Filed 4–30–15; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

**[Docket No. APHIS–2015–0024]**

### Notice of Request for Approval of an Information Collection; Volunteer Service Agreements and Volunteer Service Time and Attendance Record

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** New information collection; comment request.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection associated with volunteer service agreements and volunteer service time and attendance record.

**DATES:** We will consider all comments that we receive on or before June 30, 2015.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docket Detail;D=APHIS-2015-0024.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0024, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0024* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** For information on volunteer service agreements and volunteer service time and attendance record, contact Ms. Beverly Cassidy, HR Specialist, HR Policy, HRD, APHIS, 4700 River Road Unit 21, Riverdale, MD, 20737; (301) 851–2914. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**SUPPLEMENTARY INFORMATION:**

*Title:* Volunteer Service Agreements and Volunteer Service Time and Attendance Record.

*OMB Control Number:* 0579–XXXX.

*Type of Request:* Approval of a new information collection.

*Abstract:* Section 1526 of the Food and Agricultural Act of 1981 (7 U.S.C. 2272) permits the Secretary of Agriculture to establish a program to use volunteers to carry out U.S. Department of Agriculture (USDA) programs. Departmental Regulation No. 4230–1, Volunteer Programs, provides the guidelines USDA agencies must use for acceptance of volunteers and sets a requirement for agencies to publish their guidelines. Regulations of the Office of Personnel Management (OPM) in 5 CFR part 308 provide agencies with the authority to establish programs designed to provide educationally related work assignments for students in nonpay status.

The Marketing and Regulatory Programs (MRP) mission area of USDA uses several information collection activities to assist MRP program officials, administrative personnel, and USDA Human Resources offices in determining a volunteer's eligibility and suitability for volunteer service. The information is necessary to facilitate establishment of guidelines for acceptance of volunteer services; make a determination of an individual's eligibility and suitability to serve as a volunteer in MRP; and comply with OPM regulations requiring documentation of volunteer service and maintenance of records. The information collection activities include a Student Volunteer Service Agreement, Nonstudent Volunteer Service Agreement, and Volunteer Time and Attendance Record.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

*Estimate of burden:* The public reporting burden for this collection of information is estimated to average 0.22 hours per response.

*Respondents:* Individuals engaged in activities for which they are not paid, except for authorized expenses associated with performance of volunteer activities.

*Estimated annual number of respondents:* 85.

*Estimated annual number of responses per respondent:* 2.

*Estimated annual number of responses:* 170.

*Estimated total annual burden on respondents:* 38 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 27th day of April 2015.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015–10193 Filed 4–30–15; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

**[Docket No. APHIS–2015–0026]**

### General Conference Committee of the National Poultry Improvement Plan

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** We are giving notice of a meeting of the General Conference

Committee of the National Poultry Improvement Plan.

**DATES:** The General Conference Committee meeting will be held on July 23, 2015, 7:30 a.m. to 12:30 p.m.

**ADDRESSES:** The meeting will be held at the Little America Hotel, 500 South Main Street, Salt Lake City, UT 84101.

**FOR FURTHER INFORMATION CONTACT:** Dr. Denise Brinson, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094; (770) 922–3496.

**SUPPLEMENTARY INFORMATION:** The General Conference Committee (the Committee) of the National Poultry Improvement Plan, representing cooperating State agencies and poultry industry members, serves an essential function by acting as liaison between the poultry industry and the Department in matters pertaining to poultry health.

Topics for discussion at the upcoming meeting include:

1. Approved tests,

2. National Veterinary Services Laboratories avian influenza update,

3. Salmonella update,

4. Mycoplasma update, and

5. U.S. Department of Agriculture updates.

The meeting will be open to the public. However, due to time constraints, the public will not be allowed to participate in the discussions during the meeting. Written statements on meeting topics may be filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Statements filed with the Committee should specify that they pertain to the July 2015 Committee meeting. Written statements may also be filed at the meeting.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Done in Washington, DC, this 27th day of April 2015.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2015–10196 Filed 4–30–15; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Revision of Land and Resource Management Plan for Flathead National Forest and an Amendment of the Helena, Kootenai, Lewis and Clark, and Lolo National Forest Plans To Incorporate Relevant Direction From the Northern Continental Divide Ecosystem Grizzly Bear Conservation Strategy

**AGENCY:** Forest Service, USDA.

**ACTION:** Extension of comment period.

**SUMMARY:** The Forest Service published a notice of intent to prepare an environmental impact statement in the **Federal Register** on March 6, 2015, initiating a 60-day comment period on the proposed action to revise the land and resource management plan (forest plan) of the Flathead National Forest and amend the forest plans of the Helena, Kootenai, Lewis and Clark, and Lolo National Forest Plans to incorporate relevant direction from the Northern Continental Divide Ecosystem Grizzly Bear Conservation Strategy. The closing date for that 60-day comment period is May 5, 2015; the Agency is extending the comment period for an additional 10 days.

**DATES:** Comments must be received by May 15, 2015.

**ADDRESSES:** Send or deliver written comments to the Flathead National Forest Supervisor's Office, Attn: Forest Plan Revision, 650 Wolfpack Way, Kalispell, Montana 59901. Comments may also be sent via email to *flatheadplanrevision@fs.fed.us* or via facsimile to (406) 758–5379. Further instructions for providing comments that will assist the planning team in reviewing comments can be found on the Flathead National Forest Web site *www.fs.usda.gov/goto/flathead/fpr.*

**FOR FURTHER INFORMATION CONTACT:** Joe Krueger, Forest Planner, Flathead National Forest, 650 Wolfpack Way, Kalispell, Montana 59901, (406) 758–5243, or at *flatheadplanrevision@fs.fed.us.* Information regarding the Flathead NF plan revision is available on the Forest's Plan Revision Web site at: *www.fs.usda.gov/goto/flathead/fpr;* information about the amendment is available at *www.fs.usda.gov/goto/flathead/gbamend.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** As directed by the National Forest Management Act, the U. S. Department of Agriculture, Forest Service, is preparing the Flathead National Forest's revised forest plan and an amendment to provide relevant direction from the Northern Continental Divide Ecosystem (NCDE) Grizzly Bear Conservation Strategy into the forest plans for the Helena, Kootenai, Lewis and Clark and Lolo National Forests. The Forest Service will prepare a single environmental impact statement (EIS) for its revised forest plan and the amendment.

The revised Flathead forest plan will supersede the existing forest plan that was approved by the Regional Forester in 1986, and amended more than 20 times since. The existing Flathead forest plan will remain in effect until the revised forest plan takes effect. The management direction pertaining to grizzly bear within the current forest plans of the Helena National Forest, approved by the Regional Forester in 1986; Kootenai National Forest, approved by the Regional Forester in 2015; Lewis and Clark National Forest, approved by the Regional Forester in 1986; and Lolo National Forest, approved by the Regional Forester in 1986, as amended, will remain in effect until the proposed amendment takes effect.

In response to this notice, we are asking for comments on the proposed action so we may refine the proposed action and identify possible alternatives to the proposed action. Comments concerning the scope of the proposed action must be received by May 15, 2015. The draft EIS is expected in January 2016 and the final EIS is expected in June 2017.

The Flathead National Forest plan revision Web site (*www.fs.usda.gov/goto/flathead/fpr)* provides the full text of the proposed action, describing preliminary desired conditions, objectives, standards, guidelines, and other plan content; the 2014 Assessment; summaries of the public meetings and public meeting materials; and public comments. The forest plan amendment component of the proposed action for the Helena, Kootenai, Lewis and Clark, and Lolo National Forests is located at *www.fs.usda.gov/goto/flathead/gbamend,* which can be linked from the individual Forest's Web sites as well. The material available on these sites may be updated or revised at any time as part of the planning process.

The 2012 Planning Rule is explained in more detail on the Forest Service's Web site at *http://www.fs.usda.gov/detail/planningrule/home/*

*?cid=stelprdb5359471.* The draft NCDE Grizzly Bear Conservation Strategy is currently available on the U.S. Fish and Wildlife Service's Web site at *http://www.fws.gov/mountain-prairie/species/mammals/grizzly/continental index.html.*

Dated: April 27, 2015.

**Sharon LaBrecque,**

*Acting Forest Supervisor, Flathead National Forest.*

[FR Doc. 2015–10213 Filed 4–30–15; 8:45 am]

**BILLING CODE 3410–11–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Black Hills National Forest Advisory Board Meeting

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972, the Forest and Rangeland Renewable Resources Planning Act of 1974, the National Forest Management Act of 1976, and the Federal Public Lands Recreation Enhancement Act. Additional information concerning the Board, including the meeting summary/minutes, can be found by visiting the Board's Web site at: *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees.*

**DATES:** The meeting will be held Wednesday, May 20, 2015 at 1:00 p.m.

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

**ADDRESSES:** The meeting will be held at the Mystic Ranger District, 8221 South Highway 16, Rapid City, South Dakota. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Black Hills National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Scott Jacobson, Committee Coordinator, by phone at 605–673–9216, or by email at *sjjacobson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to provide:

(1) Motorized Travel/Over Snow Working Group Update; and

(2) Black Backed Woodpecker Update; and

(3) Northern Long Eared Bat Listing Update; and

(4) Recreation Facility/Enterprise Team Update.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by May 4, 2015 to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Board may file written statements with the Board's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Scott Jacobson, Black Hills National Forest Supervisor's Office, 1019 North Fifth Street, Custer, South Dakota 57730; by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208.

*Meeting Accommodations:* If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: April 27, 2015.

**Craig Bobzien,**

*Forest Supervisor.*

[FR Doc. 2015–10290 Filed 4–30–15; 8:45 am]

**BILLING CODE 3411–15–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–24–2015]**

### Foreign-Trade Zone (FTZ) 7—Mayaguez, Puerto Rico; Notification of Proposed Production Activity; Neolpharma, Inc.; Subzone 7O; (Pharmaceutical Products); Caguas, Puerto Rico

The Puerto Rico Industrial Development Company, grantee of FTZ 7, submitted a notification of proposed production activity to the FTZ Board on behalf of Neolpharma, Inc. (Neolpharma), operator of Subzone 7O in Caguas, Puerto Rico. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on April 20, 2015.

Neolpharma already has authority to produce clarithromycin, azithromycin, levothyroxine, hydroxyzine pamoate and hydroxyzine hydrochloride. The current request would add finished products and foreign-status materials to the scope of authority. Neolpharma may produce its own products or provide contract manufacturing operations for other companies.

Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Neolpharma from customs duty payments on the foreign-status materials and components used in export production. On its domestic sales, Neolpharma would be able to choose the duty rate (duty-free) during customs entry procedures that applies to the final products (whether in brand name or generic form)—Doxycycline capsules; Calan SR™; Celebrex™; Geodon HFC™; Ziprasidone HFC; Norpace CR™ and Norpace IR™—for the foreign status materials noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The materials sourced from abroad include: Microcrystalline cellulose; disopyramide phosphate USP; and, lactose monohydrate (duty rate ranges from 5.2% to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is June 10, 2015.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

**FOR FURTHER INFORMATION CONTACT:** Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: April 23, 2015.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2015–10168 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[S–59–2015]**

### Foreign-Trade Zone 154—Baton Rouge, Louisiana; Application for Subzone; Syngenta Crop Protection LLC, St. Gabriel and Baton Rouge, Louisiana

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Greater Baton Rouge Port Commission, grantee of FTZ 154, requesting subzone status for the facilities of Syngenta Crop Protection LLC located in St. Gabriel and Baton Rouge, Louisiana. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on April 27, 2015.

The proposed subzone would consist of the following sites: *Site 1* (300 acres)—St. Gabriel Plant, 3905 Highway 75, St. Gabriel; *Site 2* (9.6 acres)—Ace Warehouse, 1849 River Road South, Baton Rouge; *Site 3* (1 acre)—Ace Warehouse, 125 S. 14th Street, Baton Rouge; and, *Site 4* (4.15 acres)—Baton Rouge Warehouse, 1565 River Road South, Baton Rouge. The proposed subzone would be subject to the existing activation limit of FTZ 154. A notification of proposed production activity has been submitted and will be published separately for public comment.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is June 10, 2015. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to June 25, 2015.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: April 27, 2015.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2015–10254 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**Background**

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

**Upcoming Sunset Reviews for June 2015**

The following Sunset Reviews are scheduled for initiation in June 2015 and will appear in that month's Notice of Initiation of Five-Year Sunset Review (''Sunset Review'').

| | Department contact |
|---|---|
| **Antidumping Duty Proceedings** | |
| Potassium Phosphate Salts from China, (A–570–962) (1st Review) | Matthew Renkey, (202) 482–2312. |
| Steel Grating from China, (A–570–947) (1st Review) | Matthew Renkey, (202) 482–2312. |
| Tissue Paper Products from China, (A–570–894) (2nd Review) | David Goldberger, (202) 482–4136. |
| **Countervailing Duty Proceedings** | |
| Potassium Phosphate Salts from China, (C–570–963) (1st Review) | Jacqueline Arrowsmith, (202) 482–5255. |
| Steel Grating from China, (C–570–948) (1st Review) | Jacqueline Arrowsmith, (202) 482–5255. |

*Suspended Investigations*

No Sunset Review of suspended investigations is scheduled for initiation in June 2015.

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The Notice of Initiation of Five-Year (''Sunset'') Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: April 22, 2015.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2015–10249 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Civil Nuclear Energy Export Opportunity Seminar

**AGENCY:** International Trade Administration, DOC.

**ACTION:** Notice of Civil Nuclear Energy Export Opportunity Seminar.

**SUMMARY:** This notice sets forth the proposed agenda for a Civil Nuclear Energy Export Opportunity Seminar.

**DATES:** The meeting is scheduled for Monday, May 11, 2015, at 1:00 p.m. Pacific Daylight Time (PDT).

**ADDRESSES:** The meeting will be held at the Washington Athletic Club, 1325 Sixth Ave, Seattle, WA 98101.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jonathan Chesebro, Office of Energy & Environmental Industries, ITA, Room 4053, 1401 Constitution Ave. NW., Washington, DC 20230. (Phone: 202–482–1297; Fax: 202–482–5665; email: *jonathan.chesebro@trade.gov*).

**SUPPLEMENTARY INFORMATION:**

#### Background

Hosted by the U.S. Department of Energy, National Nuclear Security Administration (NNSA), the purpose of this event is to provide a forum for U.S. Government (USG) officials to brief companies on recent developments in U.S. civil nuclear export controls, 123 Agreements for Peaceful Nuclear Cooperation, and export market opportunities. There will also be a Question and Answer session regarding these topics. This is an opportunity to hear from USG experts on these topics to get information on U.S. civil nuclear export opportunities. Additional Export Opportunity Seminars will be scheduled in other U.S. cities in the next few months.

Topics to be considered: The agenda for the Monday, May 11, 2015 Civil Nuclear Energy Export Opportunity Seminar is as follows:

1:00 p.m.–5:00 p.m.

1:00–1:15—Introduction—USG Support for the U.S. Civil Nuclear Industry
U.S. Department of Commerce, International Trade Administration (ITA), Office of Energy & Environmental Technologies

1:15–1:45—123 Agreements for Peaceful Nuclear Cooperation
Richard Stratford—Director, Office of Nuclear Energy, Safety & Security—U.S. Department of State

1:45–2:30—Part 810 Export Control Rule
Rich Goorevich/Katie Strangis—U.S. Department of Energy, National Nuclear Security Administration (NNSA)

2:30–3:00—Part 110 Export Control Rule
Brooke Smith—Chief, Export Controls & Nonproliferation Branch, Nuclear Regulatory Commission (NRC)

3:00–3:30—Export Administration Regulations
Steven Clagett—Director, Nuclear and Missile Technology Division, Bureau of Industry and Security (BIS), U.S. Department of Commerce

3:30–4:00—Demonstration of Part 810 e-licensing system (e810)

4:00–5:00—Question & Answer Session

The meeting will be disabled-accessible. Seating is limited and available on a first-come, first-served basis.

#### How to RSVP

Email your name, title and organization to *jonathan.chesebro@trade.gov* by 5:00 p.m. Eastern Time on Friday May 8. The event is free but space is limited. Light refreshments will be provided.

**Edward A. O'Malley,**

*Director, Office of Energy and Environmental Industries.*

[FR Doc. 2015–10172 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–DR–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Civil Nuclear Trade Advisory Committee (CINTAC) Meeting

**AGENCY:** ITA, DOC.

**ACTION:** Notice of Federal Advisory Committee Meeting.

**SUMMARY:** This notice sets forth the schedule and proposed agenda for a meeting of the CINTAC.

**DATES:** The meeting is scheduled for Friday, May 15, 2015, at 9:00 a.m. Eastern Standard Time (EST).

**ADDRESSES:** The meeting will be held in Room 4830, U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Ave. NW., Washington, DC 20230.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jonathan Chesebro, Office of Energy & Environmental Industries, ITA, Room 4053, 1401 Constitution Ave. NW., Washington, DC 20230. (Phone: 202–482–1297; Fax: 202–482–5665; email: *jonathan.chesebro@trade.gov*).

**SUPPLEMENTARY INFORMATION:**

*Background:* The CINTAC 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.), in response to an identified need for consensus advice from U.S. industry to the U.S. Government regarding the development and administration of programs to expand United States exports of civil nuclear goods and services in accordance with applicable U.S. laws and regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities will affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

*Topics to be considered:* The agenda for the Friday, May 15, 2015 CINTAC meeting is as follows:

9:00 a.m.–4:00 p.m.

1. International Trade Administration's Civil Nuclear Trade Initiative Update
2. Civil Nuclear Trade Promotion Activities Discussion
3. Public comment period

The meeting will be disabled-accessible. Public seating is limited and available on a first-come, first-served basis. Members of the public wishing to attend the meeting must notify Mr. Jonathan Chesebro at the contact information below by 5:00 p.m. EDT on Friday, May 8, 2015 in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time will be available for pertinent brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 30 minutes. Individuals wishing to reserve speaking time during the meeting must contact Mr. Chesebro and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5:00 p.m. EDT on Friday, May 8, 2015. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, ITA may conduct a lottery to determine the speakers. Speakers are requested to bring at least 20 copies of their oral comments for distribution to the participants and public at the meeting.

Any member of the public may submit pertinent written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to the Civil Nuclear Trade Advisory

Committee, Office of Energy & Environmental Industries, Room 4053, 1401 Constitution Ave. NW., Washington, DC 20230. 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. EDT on Friday, May 8, 2015. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

**Edward A. O'Malley,**

*Director, Office of Energy and Environmental Industries.*

[FR Doc. 2015–10173 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–DR–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**FOR FURTHER INFORMATION CONTACT:** Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

**Background**

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (''the Act''), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (''the Department'') conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting date.

**Respondent Selection**

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

**Deadline for Withdrawal of Request for Administrative Review**

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after May 2015, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

The Department is providing this notice on its Web site, as well as in its ''Opportunity to Request Administrative Review'' notices, so that interested parties will be aware of the manner in which the Department intends to exercise its discretion in the future.

*Opportunity to Request a Review:* Not later than the last day of May 2015,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in May for the following periods:

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when the Department is closed.

| | Period of review |
|---|---|
| **Antidumping Duty Proceedings** | |
| Belgium: Stainless Steel Plate in Coils, A–423–808 | 5/1/14–4/30/15 |
| Brazil: Iron Construction Castings, A–351–503 | 5/1/14–4/30/15 |
| Canada: Citric Acid and Citrate Salt, A–122–853 | 5/1/14–4/30/15 |
| India: | |
| Circular Welded Carbon Steel Pipes and Tubes, A–533–502 | 5/1/14–4/30/15 |
| Silicomanganese, A–533–823 | 5/1/14–4/30/15 |
| Indonesia: Polyethylene Retail Carrier Bags, A–560–822 | 5/1/14–4/30/15 |
| Japan: | |
| Diffusion-Annealed Nickel-Plated Flat-Rolled Steel Products, A–588–869 | 11/19/13–4/30/15 |
| Gray Portland Cement and Cement Clinker, A–588–815 | 5/1/14–4/30/15 |
| Kazakhstan: Silicomanganese, A–834–807 | 5/1/14–4/30/15 |
| Republic of Korea: Polyester Staple Fiber, A–580–839 | 5/1/14–4/30/15 |
| Socialist Republic of Vietnam: Polyester Retail Carrier Bags, A–552–806 | 5/1/14–4/30/15 |
| South Africa: Stainless Steel Plate in Coils, A–791–805 | 5/1/14–4/30/15 |
| Taiwan: | |
| Certain Circular Welded Carbon Steel Pipes and Tubes, A–583–008 | 5/1/14–4/30/15 |
| Polyester Staple Fiber, A–583–833 | 5/1/14–4/30/15 |
| Polyethylene Retail Carrier Bags, A–583–843 | 5/1/14–4/30/15 |
| Stainless Steel Plate in Coils, A–583–830 | 5/1/14–4/30/15 |
| Stilbenic Optical Brightening Agents, A–583–848 | 5/1/14–4/30/15 |
| The People's Republic of China: | |
| Aluminum Extrusions, A–570–967 | 5/1/14–4/30/15 |
| Circular Welded Carbon Quality Steel Line Pipe, A–570–935 | 5/1/14–4/30/15 |
| Citric Acid and Citrate Salt, A–570–937 | 5/1/14–4/30/15 |
| Iron Construction Castings, A–570–502 | 5/1/14–4/30/15 |
| Oil Country Tubular Goods, A–570–943 | 5/1/14–4/30/15 |
| Pure Magnesium, A–570–832 | 5/1/14—4/30/15 |
| Stilbenic Optical Brightening Agents, A–570–972 | 5/1/14–4/30/15 |
| Turkey: | |
| Circular Welded Carbon Steel Pipes and Tubes, A–489–501 | 5/1/14–4/30/15 |
| Light-Walled Rectangular Pipe and Tube, A–489–815 | 5/1/14–4/30/15 |
| United Arab Emirates: Steel Nails, A–520–804 | 5/1/14–4/30/15 |
| Venezuela: Silicomanganese, A–307–820 5/1/14–4/30/15. | |
| **Countervailing Duty Proceedings** | |
| Brazil: Iron Construction Castings,C–351–504 | 1/1/14–12/31/14 |
| Socialist Republic of Vietnam: Polyethylene Retail Carrier Bags, C–552–805 | 1/1/14–12/31/14 |
| South Africa: Stainless Steel Plate in Coils, C–791–806 | 1/1/14–12/31/14 |
| The People's Republic of China: | |
| Aluminum Extrusions, C–570–968 | 1/1/14–12/31/14 |
| Citric Acid and Citrate Salt, C–570–938 | 1/1/14–12/31/14 |
| **Suspension Agreements** | |
| None. | |

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party the Department was unable to locate in prior segments, the Department will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) the Department clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[2]

Further, as explained in *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty*

[2] *See also* the Enforcement and Compliance Web site at *http://trade.gov/enforcement/.*

*Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013), the Department clarified its practice with regard to the conditional review of the non-market economy (NME) entity in administrative reviews of antidumping duty orders. The Department will no longer consider the NME entity as an exporter conditionally subject to administrative reviews. Accordingly, the NME entity will not be under review unless the Department specifically receives a request for, or self-initiates, a review of the NME entity.[3] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, the Department will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity).

Following initiation of an antidumping administrative review when there is no review requested of the NME entity, the Department will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS'') on Enforcement and Compliance's ACCESS Web site at *http://access.trade.gov.*[4] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of May 2015. If the Department does not receive, by the last day of May 2015, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: April 22, 2015.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2015–10225 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Initiation of Five-Year (''Sunset'') Review

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating the five-year review (''Sunset Review'') of the antidumping and countervailing duty (''AD/CVD'') orders listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same orders.

**DATES:** *Effective Date:* May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

**SUPPLEMENTARY INFORMATION:**

### Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

### Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating Sunset Reviews of the following antidumping and countervailing duty orders:

| DOC case No. | ITC case No. | Country | Product | Department contact |
|---|---|---|---|---|
| A–475–820 | 731–TA–770 | Italy | Stainless Steel Wire Rod (3rd Review) | David Goldberger (202) 482–4136. |
| A–588–843 | 731–TA–771 | Japan | Stainless Steel Wire Rod (3rd Review) | David Goldberger (202) 482–4136. |
| A–580–829 | 731–TA–772 | Republic of Korea | Stainless Steel Wire Rod (3rd Review) | David Goldberger (202) 482–4136. |
| A–570–007 | 731–TA–149 | PRC | Barium Chloride (4th Review) | Matthew Renkey (202) 482–2312. |
| A–570–888 | 731–TA–1047 | PRC | Floor-Standing Metal Top Ironing Tables and Parts Thereof (2nd Review). | Jacqueline Arrowsmith (202) 482–5255. |
| A–570–945 | 731–TA–1160 | PRC | Prestressed Concrete Steel Wire Strand (1st Review). | Matthew Renkey (202) 482–2312. |

[3] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[4] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

| DOC case No. | ITC case No. | Country | Product | Department contact |
|---|---|---|---|---|
| C–570–946 | 701–TA–464 | PRC | Prestressed Concrete Steel Wire Strand (1st Review). | David Goldberger (202) 482–4136. |
| A–469–807 | 731–TA–773 | Spain | Stainless Steel Wire Rod (3rd Review) | David Goldberger (202) 482–4136. |
| A–583–828 | 731–TA–775 | Taiwan | Stainless Steel Wire Rod (3rd Review) | David Goldberger (202) 482–4136. |

With respect to the countervailing duty order on Prestressed Concrete Steel Wire Strand from China, we have advanced the initiation date of this Sunset Review upon determining that initiation of the Sunset Reviews for both of the Prestressed Concrete Steel Wire Strand orders on the same date would promote administrative efficiency.

**Filing Information**

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Department's regulations, the Department's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's Web site at the following address: ''*http://enforcement.trade.gov/sunset/.*'' All submissions in these Sunset Reviews must be filed in accordance with the Department's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''), can be found at 19 CFR 351.303.[1]

**Revised Factual Information Requirements**

This notice serves as a reminder that any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[2] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in all AD/CVD investigations or proceedings initiated on or after August 16, 2013.[3] The formats for the revised certifications are provided at the end of the *Final Rule.* The Department intends to reject factual submissions if the submitting party does not comply with the revised certification requirements.

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013), which modified two regulations related to antidumping and countervailing duty proceedings: The definition of factual information (19 CFR 351.102(b)(21), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all segments initiated on or after May 10, 2013. Review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied.

**Revised Extension of Time Limits Regulation**

On September 20, 2013, the Department modified its regulation at 19 CFR 351.302(c) concerning the extension of time limits for submissions in antidumping and countervailing duty proceedings: *Extension of Time Limits,* 78 FR 57790 (September 20, 2013). The modification clarifies that parties may request an extension of time limits before a time limit established under part 351 of the Department's regulations expires, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

**Letters of Appearance and Administrative Protective Orders**

Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d)). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (''APO'') to file an APO

[1] *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[2] *See* section 782(b) of the Act.

[3] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*'') (amending 19 CFR 351.303(g)).

application immediately following publication in the **Federal Register** of this notice of initiation. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

**Information Required From Interested Parties**

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review.[4]

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews. Consult the Department's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: April 22, 2015.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2015–10244 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–DS–P**

[4] *See* 19 CFR 351.218(d)(1)(iii).

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD711**

### Marine Mammals; File No. 18881

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

**ACTION:** Notice; issuance of permit.

**SUMMARY:** Notice is hereby given that a permit has been issued to Texas Sealife Center, 14220 South Padre Island Drive, Corpus Christi, TX 78418, [Responsible Party: Tim Tristan] to conduct research on bottlenose dolphins (*Tursiops truncatus*).

**ADDRESSES:** The permit and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

**FOR FURTHER INFORMATION CONTACT:** Amy Hapeman or Howard Goldstein, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** On February 13, 2015, notice was published in the **Federal Register** (80 FR 8060) that a request for a permit to conduct research on the species identified above had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant has been issued a permit to conduct research on bottlenose dolphins in the bay, sound, estuary and near-shore coastal waters of Texas in the northwestern Gulf of Mexico. The purpose of the research is to: (1) Develop and maintain standardized photo-identification catalogs; (2) characterize fine-scale population structure and dynamics; (3) estimate abundance for strategic stocks; (4) establish baseline patterns of distribution, habitat use, site-fidelity, diet, and contaminant loads; (5) analyze dolphin behavior in relation to anthropogenic activities; and (6) identify potential risks to the population. Researchers may conduct vessel surveys for photographic identification, focal follows, behavioral observation, and biopsy sampling. The permit is valid through April 30, 2020.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: April 28, 2015.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015–10185 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD924**

### Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting via webinar.

**SUMMARY:** The Pacific Fishery Management Council (Pacific Council) will convene a webinar meeting of its Coastal Pelagic Species Management Team (CPSMT). Information on how to participate will be posted to the Pacific Council's Web site (*www.pcouncil.org*) in advance of the webinar.

**DATES:** The webinar meeting will be held Wednesday, May 20, 2015, from 9 a.m. to 11 a.m. Pacific Daylight Time.

**ADDRESSES:** A listening station will be available at the Pacific Council office: 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

**FOR FURTHER INFORMATION CONTACT:** Kerry Griffin, Staff Officer; telephone: (503) 820–2409.

**SUPPLEMENTARY INFORMATION:** The primary purpose of the meeting is to discuss agenda items on the June 2015 Pacific Council meeting, plan for completion of the Stock Assessment and Fishery Evaluation (SAFE) document, and discuss future meeting plans.

Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the CPSMT's and CPSAS's intent to take final action to address the emergency.

**Special Accommodations**

This listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (503) 820–2280 at least 5 days prior to the meeting date.

Dated: April 28, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–10188 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–22–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Gulf of Mexico Fishery Management Council (Council); Public Meeting

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

**ACTION:** Meeting of the Gulf of Mexico Fishery Management Council.

**SUMMARY:** The Gulf of Mexico Fishery Management Council (Council) will hold a meeting of its Ad Hoc Reef Fish Headboat Advisory Panel (AP).

**DATES:** The meeting will convene on Tuesday, May 19, 2015 from 8:30 a.m. until 5 p.m.

**ADDRESSES:** The meeting will be held at the Astor Crowne Plaza New Orleans hotel, 739 Canal Street, New Orleans, LA 70130; (504) 962–0560.

*Council address:* Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

**FOR FURTHER INFORMATION CONTACT:** Dr. Assane Diagne, Economist, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *assane.diagne@gulfcouncil.org.*

**SUPPLEMENTARY INFORMATION:** The items of discussion on the agenda are as follows:

**Ad Hoc Reef Fish Headboat Advisory Panel (AP) Agenda, Tuesday, May 19, 2015, 8:30 a.m. Until 5 p.m.**

I. Adoption of Agenda
II. Election of Chair and Vice-Chair
III. Data Collection for the Southeast Headboat Survey
IV. Overview of the Headboat Component
V. Reef Fish Species To Consider
VI. Management Objectives for the Headboat Component
VII. Management Approaches To Consider
VIII. Recommendations to the Council
IX. Other Business
—Adjourn—

The Agenda is subject to change, and the latest version will be posted on the Council's file server. For meeting materials see folder ''Ad Hoc Reef Fish Headboat'' on the Gulf Council file server. To access the file server, the URL is *https://public.gulfcouncil.org:5001/webman/index.cgi,* or go to the Council's Web site and click on the FTP link in the lower left of the Council Web site (*http://www.gulfcouncil.org*). The username and password are both ''gulfguest''.

The meeting will be webcast over the Internet. A link to the webcast will be available on the Council's Web site, *http://www.gulfcouncil.org.*

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

**Special Accommodations**

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

**Note:** The times and sequence specified in this agenda are subject to change.

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

Dated: April 28, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–10190 Filed 4–30–15; 8:45 am]

BILLING CODE 3510–22–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XD900**

### Marine Mammals; File No. 18786

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

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that the NMFS Office of Protected Resources, Marine Mammal Health and Stranding Response Program (MMHSRP; Responsible Party: Teri Rowles, D.V.M., Ph.D.), 1315 East-West Highway, Silver Spring, MD 20910, has applied in due form for a permit to take, import, and export marine mammals and marine mammal parts for research and enhancement purposes.

**DATES:** Written, telefaxed, or email comments must be received on or before June 1, 2015.

**ADDRESSES:** The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 18786 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Amy Sloan or Jennifer Skidmore, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The MMHSRP proposes to: (1) Carry out response, rescue, rehabilitation and

release of threatened and endangered marine mammals under NMFS jurisdiction (Cetacea and Pinnipedia [excluding walrus]), and disentanglement of all marine mammals under NMFS jurisdiction, pursuant to sections 109(h), 112(c), and Title IV of the MMPA; and, carry out such activities as enhancement pursuant to section 10(a)(1)(A) of the ESA; (2) Conduct health-related, bona fide scientific research studies on marine mammals and marine mammal parts under NMFS jurisdiction pursuant to sections 104(c) and Title IV of the MMPA and section 10(a)(1)(A) of the ESA, including research related to emergency response that may involve compromised animals, and research on healthy animals that have not been subject to emergency response (*e.g.,* baseline health studies); (3) Conduct Level B harassment on all marine mammal species under NMFS jurisdiction incidental to MMHSRP activities in the U.S.; and (4) Collect, salvage, receive, possess, transfer, import, export, analyze, and curate marine mammal specimens under NMFS jurisdiction for purposes delineated in numbers (1) and (2) above.

Procedures proposed to carry out the activities include but are not limited to: Close approach via ground, vessel, and aerial surveys (manned and unmanned); hazing and attractants; capture, restraint, and handling; administration of drugs including anesthesia, medical treatments, vaccinations; attachment of scientific instruments; marking (temporary and permanent including freeze- and hot-branding); disentanglement and de-hooking; rehabilitation, transport, and release; biological sampling and analyses; auditory brainstem response/auditory evoked potential; active acoustic playbacks; unintentional mortality and euthanasia; and import and export activities. The permit is requested for a 5-year period.

In compliance with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*), an initial determination has been made that the majority of activities proposed are consistent with the Preferred Alternative in the 2009 Final Programmatic Environmental Impact Statement (PEIS) for the Marine Mammal Health and Stranding Response Program. Also, a draft environmental assessment (EA) has been prepared in compliance with NEPA to examine whether significant environmental impacts could result from permitting new activities (hot branding, UAS, and vaccinations), which were not considered in the Final PEIS. The draft EA is available for review and comment simultaneously with the permit application.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: April 28, 2015.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015–10186 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–22–P**

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### New England Fishery Management Council; Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The New England Fishery Management Council (Council) is scheduling a public meeting of its Scientific & Statistical Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

**DATES:** This meeting will be held on Wednesday, May 20, 2015 at 9 a.m.

**ADDRESSES:** The meeting will be held at the Four Points by Sheraton, 407 Squire Road, Revere, MA 02151; telephone: (781) 284–7200; fax: (781) 289–3176.

*Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

**FOR FURTHER INFORMATION CONTACT:** Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

**SUPPLEMENTARY INFORMATION:**

#### Agenda Items

The Committee will review the results of the recent operational stock assessment for Atlantic herring and develop recommendations for acceptable biological catch (ABC) for the 2016–18 fishing years, as well as other related recommendations. The Committee may not develop all of the recommendations for this stock at one meeting.

They will review/discuss progress of Ecosystem-Based Fisheries Management (EBFM) Plan Development Team (PDT) towards developing ecological guidance for the Council to consider when developing alternatives for the Atlantic herring ABC control rule in Amendment 8 to the Herring FMP. The committee may review and add to the comments it provided the Council on the proposed revisions to the Magnuson-Stevens Act National Standard Guidelines 1, 3, 5 and 7. They will address other business as necessary.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

#### Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: April 28, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–10189 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–22–P**

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Gulf of Mexico Fishery Management Council; Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The Gulf of Mexico Fishery Management Council (Council) will hold a meeting of its Standing and Special Reef Fish Scientific and Statistical Committees (SSC).

**DATES:** The meeting will convene on Wednesday, May 20, 2015, from 8:30 a.m. to 5 p.m.

**ADDRESSES:** The meeting will be held at the Astor Crowne Plaza New Orleans

hotel, 739 Canal Street, New Orleans, LA 70130; telephone: (504) 962–0560.

*Council address:* Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

**FOR FURTHER INFORMATION CONTACT:** Mr. Steven Atran, Senior Fishery Biologist, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *steven.atran@gulfcouncil.org*.

**SUPPLEMENTARY INFORMATION:** The items of discussion in the individual meeting agenda are as follows:

**Standing and Special Reef Fish Scientific and Statistical Committees (SSC) Agenda, Wednesday, May 20, 2015, 8:30 a.m. Until 5 p.m.**

I. Introductions and Adoption of Agenda
II. Approval of the Standing and Special Reef Fish Portion of the March 10–12, 2015 Standing, Special Spiny Lobster and Special Reef Fish SSC Minutes
III. Selection of SSC Representative at June, 2015 Council Meeting
IV. Analysis of Alternative $F_{MSY}$ Proxies for *Red Snapper*
V. Review of the Effect of Recalibrated Recreational Removals and Recreational Selectivity on Estimates of Overfishing Limits (OFL), Acceptable Biological Catch (ABC), and Maximum Sustainable Yield (MSY) for Gulf *Red Snapper*
VI. Evaluation of Recent Trends in *Gag* Catch Per Unit Effort (CPUE) Indices
VII. *Hogfish* OFL and ABC
  a. OFL and ABC Recommendations for Gulf Stock
  b. Review of South Atlantic SSC OFL and ABC Recommendations for Florida Keys/South Atlantic stock
VIII. *Mutton Snapper* OFL and ABC
  a. Review of Age-Length Keys vs. Direct Age Sensitivity Runs
  b. Review of South Atlantic SSC OFL and ABC Recommendations
  c. Gulf SSC Concurrence or Selection of Alternative OFL and ABC
IX. Other Business
—Adjourn—

The Agenda is subject to change, and the latest version will be posted on the Council's file server. To access the file server, the URL is *https://public.gulfcouncil.org:5001/webman/index.cgi,* or go to the Council's Web site and click on the FTP link in the lower left of the Council Web site (*http://www.gulfcouncil.org*). The username and password are both ''gulfguest''. Click on the ''Library Folder'', then scroll down to ''SSC meeting—2015–05''.

The meeting will be webcast over the internet. A link to the webcast will be available on the Council's Web site, *http://www.gulfcouncil.org.*

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committees will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

**Special Accommodations**

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

**Note:** The times and sequence specified in this agenda are subject to change.

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

Dated: April 28, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015–10191 Filed 4–30–15; 8:45 am]

**BILLING CODE 3510–22–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List; Deletions

**AGENCY:** Committee for Purchase from People Who are Blind or Severely Disabled.

**ACTION:** Deletions from the Procurement List.

**SUMMARY:** This action deletes products from the Procurement List that were previously furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

**DATES:** *Effective:* 6/1/2015.

**ADDRESSES:** Committee for Purchase from People Who are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

**FOR FURTHER INFORMATION CONTACT:** Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:**

**Deletions**

On 3/27/2015 (80 FR 16363–16364), the Committee for Purchase from People Who are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

**Regulatory Flexibility Act Certification**

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

**End of Certification**

Accordingly, the following products are deleted from the Procurement List:

*Products*

*Product Name/NSN(s):* Tray, Desk, Plastic, 7520–01–466–0483, 7520–01–094–4310—Side Loading, Stackable, Legal, Beige
*Mandatory Source of Supply:* LC Industries, Inc., Durham, NC
*Contracting Activity:* General Services Administration, New York, NY

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2015–10211 Filed 4–30–15; 8:45 am]

**BILLING CODE 6353–01–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List; Proposed Additions and Deletions

**AGENCY:** Committee for Purchase from People Who are Blind or Severely Disabled.

**ACTION:** Proposed Additions to and Deletions from the Procurement List.

**SUMMARY:** The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities and delete services previously furnished by such agencies.

**DATES:** *Comments Must be Received on or before:* 6/1/2015.

**ADDRESSES:** Committee for Purchase from People Who are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

**FOR FURTHER INFORMATION CONTACT:** *For Further Information or to Submit Comments Contact:* Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

## Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

*Products*

*Product Name/NSN:* File Folder, Single Tab, ⅓ Cut.
7530–00–NIB–1104—Letter, Position 1
*Distribution:* A-List
*Mandatory Purchase for:* Total Government Requirement
*Mandatory Source of Supply:* Association for Vision Rehabilitation and Employment, Inc., Binghamton, NY
*Contracting Activity:* General Services Administration, New York, NY

*Product Name/NSN(s):* Pen, Retractable Gel
7520–00–NIB–2235—Black Ink, Fine Point
7520–00–NIB–2236—Blue Ink, Fine Point
7520–00–NIB–2135—Black Ink, Medium Point
7520–00–NIB–2136—Blue Ink, Medium Point
*Distribution:* A-List
7520–00–NIB–2237—Black Ink, Bold Point
7520–00–NIB–2238—Blue Ink, Bold Point
*Distribution:* B-List
*Mandatory Purchase for:* Total and Broad Government Requirements
*Mandatory Source of Supply:* Industries of the Blind, Inc., Greensboro, NC
*Contracting Activity:* General Services Administration, New York, NY

*Product Name/NSN(s):* Bag, Shopping Tote, Laminated
MR 400—Small, ''Live Spicy''
MR 401—Small, ''Live Fresh''
MR 402—Small, ''Live Sweet''
MR 403—Small, ''Live Well''
MR 404—Large, ''Live Spicy''
MR 405—Fresh, ''Live Fresh''
MR 406—Large, ''Live Sweet''
MR 407—Large, ''Live Well''
*Distribution:* C-List
*Mandatory Purchase for:* Requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency
*Mandatory Source of Supply:* Industries for the Blind, Inc., West Allis, WI
*Contracting Activity:* Defense Commissary Agency, Fort Lee, VA

*Service*

*Service Type:* Contract Management Support Service
*Mandatory Purchase for:* National Institutes of Health (NIH), Rockville, MD
*Mandatory Source of Supply:* Columbia Lighthouse for the Blind, Washington, DC
*Contracting Activity:* Department of Health and Human Services, Office of Logistics and Acquisition Operations, Rockville, MD

## Deletions

The following services are proposed for deletion from the Procurement List:

**Services**

*Service Type:* Grounds Maintenance Service
*Mandatory Purchase for:* Ballsfield, Fort Ord, CA
*Mandatory Source of Supply:* Unknown
*Contracting Activity:* Dept of the Army, W40M Northern Region Contract Office, Fort Belvoir, VA

*Service Type:* Shelf Stocking & Custodial Service
*Mandatory Purchase for:* Barbers Point Naval Air Station, Barbers Point, HI
*Mandatory Source of Supply:* Trace, Inc., Boise, ID
*Contracting Activity:* Defense Commissary Agency, Fort Lee, VA

**Barry S. Lineback,**
*Director, Business Operations.*

[FR Doc. 2015–10210 Filed 4–30–15; 8:45 am]
BILLING CODE 6353–01–P

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## DEPARTMENT OF EDUCATION

**[Docket No. ED–2015–ICCD–0011]**

## Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Assurance of Compliance—Civil Rights Certificate

**AGENCY:** Office of Civil Rights (OCR), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before June 1, 2015.

**ADDRESSES:** Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0011 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Elizabeth Wiegman, 202–453–6039.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* Assurance of Compliance—Civil Rights Certificate.

*OMB Control Number:* 1870–0503.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* Private Sector, State, Local and Tribal Governments.

*Total Estimated Number of Annual Responses:* 25.

*Total Estimated Number of Annual Burden Hours:* 4.

*Abstract:* The Office for Civil Rights (OCR) has enforcement responsibilities under several civil rights laws, including Title VI, Title IX, Section 504, the Age Discrimination Act, and the Boy Scouts of America Equal Access Act. To meet these responsibilities, OCR collects assurances of compliance from applicants for Federal financial assistance from, and applicants for funds made available through, the Department of Education, as required by regulations. These entities include, for example, State educational agencies, local education agencies, and postsecondary educational institutions. If a recipient violates one or more of these civil rights laws, OCR and the Department of Justice can used the signed assurances of compliance in an enforcement proceeding.

Dated: April 27, 2015.

**Stephanie Valentine,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–10159 Filed 4–30–15; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2015–ICCD–0056]**

### Agency Information Collection Activities; Comment Request; An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior (MTSS–B)

**AGENCY:** Institute of Education Sciences/ National Center for Education Statistics (IES), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

**DATES:** Interested persons are invited to submit comments on or before June 30, 2015.

**ADDRESSES:** Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0056 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will only accept comments during the comment period in this mailbox when the regulations.gov site is not available. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Lauren Angelo, (202) 219–2180.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior (MTSS–B).

*OMB Control Number:* 1850–NEW.

*Type of Review:* A new information collection.

*Respondents/Affected Public:* Individuals or Households.

*Total Estimated Number of Annual Responses:* 18,820.

*Total Estimated Number of Annual Burden Hours:* 17,691.

*Abstract:* This submission requests approval of data collection activities that will be used to support An Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior (MTSS–B). The evaluation will estimate the impact on school staff practices, school climate and student outcomes of providing training and support in the MTSS–B framework plus universal (Tier I) positive behavior supports and a targeted (Tier II) intervention.

Dated: April 27, 2015.

**Stephanie Valentine,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer (OCPO), Office of Management.*

[FR Doc. 2015–10131 Filed 4–30–15; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2015–ICCD–0057]**

### Agency Information Collection Activities; Comment Request; What Works Clearinghouse Formative Feedback

**AGENCY:** Institute of Education Sciences/ National Center for Education Statistics (IES), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before June 30, 2015.

**ADDRESSES:** Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0057 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will only accept comments during the comment period in this mailbox when the regulations.gov site is not available. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance

Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Vanessa Anderson, 202–219–1310.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* What Works Clearinghouse Formative Feedback.

*OMB Control Number:* 1850–0788.

*Type of Review:* A revision of an existing information collection.

*Respondents/Affected Public:* Individuals or Households.

*Total Estimated Number of Annual Responses:* 84,630.

*Total Estimated Number of Annual Burden Hours:* 1,729.

*Abstract:* The Institute of Education Sciences (IES) within the U.S. Department of Education is proposing data collection activity as part of the What Works Clearinghouse Feedback Task. The task and its associated efforts are being undertaken by the U.S. Department of Education, Institute of Education Sciences (IES), and are being conducted by Mathematica Policy Research. The intended purpose of the Department of Education (ED), Institute of Education Sciences (IES) WWC feedback task is to collect feedback from users on the relevance, timeliness, quality, and ease of use of the products associated with the What Works Clearinghouse Web site. The results of the data collection will be used to inform improvements in ED program products and services for its customers. The WWC provides educators, policymakers, and the public with a central and trusted source of scientific evidence of what works in education. The WWC aims to make findings from education research easy and accessible through its searchable online repository of intervention reports, single study reviews, and practice guides. There are thousands of empirical studies that claim to identify effective instructional approaches, many using complicated research methods and statistical analyses. This research often yields conflicting results, leaving educators wondering which approach to take. Given the large volume of education research and significant variations in quality, principals and other educators need help identifying reliable research and interpreting findings. Using systematic review processes and evidence standards, the WWC reviews all the research on a topic to identify the most rigorous studies and synthesize the findings from high-quality education research. The WWC has developed three new products that focus on utilizing the WWC and the WWC resources when making key decisions in education. First, the WWC will produce and is developing several videos that describe the purpose of the WWC or how to understand specific materials on the Web site. For example, the WWC has already released a video that addresses how to select a mathematics curriculum. The WWC also developed practice guide summaries which consolidate the information from practice guides into an 8–10 page summary that presents expert recommendations from the field, along with tips on implementing the recommendations. The WWC has already released two of these summaries—Teaching Math to Young Children and Teaching Elementary School Students to Be Effective Writers. Finally, topical blasts consolidate WWC content relevant to a specific education topic. Emails direct users to a dedicated landing page containing links to the relevant content. Findings from the case studies of these topics will be used to improve these and other WWC products going forward. The WWC feedback task will include the following data collection methods: Focus groups with WWC users, user feedback Web surveys, and data analytics.

Dated: April 28, 2015.

**Stephanie Valentine,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–10192 Filed 4–30–15; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP15–161–000]**

### Roadrunner Gas Transmission, LLC; Notice of Application

Take notice that on April 9, 2015, Roadrunner Gas Transmission, LLC (Roadrunner), 100 W. 5th Street, Tulsa, Oklahoma 74103, filed an application pursuant to section 3 of the Natural Gas Act and part 153 of the Commission's regulations, for an order authorizing construction of new border crossing natural gas pipeline facilities for the exportation of up to 875,000 Mcf per day of natural gas at the International Boundary between the United States and Mexico in El Paso County, Texas, and for the issuance of a Presidential Permit for those facilities, 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 this application should be directed Denise Adams, Manager Rates and Regulatory Analysis ONEOK Partners, L.P. 100 West 5th Street, ONEOK Plaza, Tulsa, Oklahoma, or call (918) 732–1408, or fax (918) 732–1363, or by email *Denise.Adams@oneok.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record

for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

*Comment Date:* May 13, 2015.

Dated: April 22, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–10222 Filed 4–30–15; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 13511–002]**

### Igiugig Village Council; Notice of Intent To File License Application, Filing of Draft Application, Request for Waivers of Integrated Licensing Process Regulations Necessary for Expedited Processing of a Hydrokinetic Pilot Project License Application, and Soliciting Comments

a. *Type of Filing:* Notice of Intent to File a License Application for an Original License for a Hydrokinetic Pilot Project.

b. *Project No.:* 13511–002.

c. *Date Filed:* April 1, 2015.

d. *Submitted By:* Igiugig Village Council (Igiugig).

e. *Name of Project:* Igiugig Hydrokinetic Project.

f. *Location:* On the Kvichak River in the Lake and Peninsula Borough, near the town of Igiugig, Alaska.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Applicant Contact:* Nathan Johnson, Ocean Renewable Power Company, 66 Pearl Street, Suite 301, Portland, Maine 04101; (207) 772–7707.

i. *FERC Contact:* Dianne Rodman at (202) 502–6077 or email at *dianne.rodman@ferc.gov.*

j. *Igiugig has filed with the Commission:* (1) A notice of intent (NOI) to file an application for an original license for a hydrokinetic pilot project and a draft license application with monitoring plans; (2) a request for waivers of the integrated licensing process regulations necessary for expedited processing of a hydrokinetic pilot project license application; (3) a proposed process plan and schedule; (4) a request to be designated as the non-federal representative for section 7 of the Endangered Species Act (ESA) consultation; and (5) a request to be designated as the non-federal representative for section 106 consultation under the National Historic Preservation Act (NHPA) (collectively the pre-filing materials).

k. With this notice, we are soliciting comments on the pre-filing materials listed in paragraph j above, including the draft license application and monitoring plans. All comments should be sent to the address above in paragraph h and filed with the Commission. All comments 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 at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Any individual or entity interested in submitting comments on the pre-filing materials must do so by May 23, 2015.

l. With this notice, we are approving Igiugig's request to be designated as the non-federal representative for section 7 of the ESA and its request to initiate consultation under section 106 of the NHPA; and recommending that it begin informal consultation with: (a) The U.S. Fish and Wildlife Service and the National Marine Fisheries Service as required by section 7 of ESA; and (b) the Alaska State Historic Preservation Officer, as required by section 106 of the NHPA and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

m. With this notice, we also are asking federal, state, local, and tribal agencies with jurisdiction and/or expertise with respect to environmental issues to cooperate with us in the preparation of the environmental

document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in paragraph ''k'' above.

n. This notice does not constitute the Commission's approval of Igiugig's request to use the Pilot Project Licensing Procedures. Upon its review of the project's overall characteristics relative to the pilot project criteria, the draft license application contents, and any comments filed, the Commission will determine whether there is adequate information to conclude the pre-filing process.

o. The proposed Igiugig Hydrokinetic Project would consist of: (1) An in-stream 20- kilowatt (kW), 64-foot-long, 11-foot-high, 43-foot-wide pontoon-mounted RivGen Power System Turbine Generator Unit (TGU) in Phase 1; (2) an additional in-stream 20-kW pontoon-mounted TGU in Phase 2; (3) two anchoring systems consisting of a 13,000-pound anchor, chain, shackles, and 150 feet of mooring; (4) a 375-foot-long, coated and weighted combined power, data, and environmental monitoring cable from the TGU for Phase 1; and a 675-foot-long cable from the TGU for Phase 2; (5) an existing 10-foot-long by 8-foot-wide shore station for housing project electronics and controls; and (6) appurtenant facilities. The project is estimated to have an annual generation of 409,504 kilowatt-hours per year.

p. A copy of the draft license application and all pre-filing materials are 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 (P–13511), 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.

q. *Pre-filing process schedule.* The pre-filing process will be conducted pursuant to the following tentative schedule. Revisions to the schedule below may be made based on staff's review of the draft application and any comments received.

| Milestone | Date |
|---|---|
| Comments on pre-filing materials due. | May 23, 2015. |
| Issuance of meeting notice (if needed). | June 7, 2015. |
| Public meeting/technical conference (if needed). | June 22, 2015. |

r. 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.

Dated: April 23, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–10219 Filed 4–30–15; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 13806–004]**

### 5440 Hydro Inc.; Notice of Application Accepted for Filing With the Commission, Intent To Waive Scoping, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Terms and Conditions, and Recommendations, and Establishing an Expedited Schedule for Processing

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Exemption From Licensing.

b. *Project No.:* P–13806–004.

c. *Date filed:* July 28, 2014.

d. *Applicant:* 5440 Hydro Inc.

e. *Name of Project:* Brooklyn Dam Hydroelectric Project.

f. *Location:* On the Upper Ammonoosuc River, in the Town of Northumberland, Coos County, New Hampshire. The project would not occupy lands of the United States.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708.

h. *Applicant Contact:* Lutz Loegters, 5440 Hydro Inc., 717 Atlantic Avenue, Suite 1A, Boston, Massachusetts 02111, (416) 643–6615.

i. *FERC Contact:* John Ramer, (202) 502–8969, *john.ramer@ferc.gov.*

j. *Deadline for filing motions to intervene and protests, comments, terms and conditions, and recommendations:* Due to the small size and location of this project and the close coordination with state and federal agencies during preparation of the application, the 60-day timeframe in 18 CFR 4.34(b) is shortened. Instead, motions to intervene and protests, comments, terms and conditions, and recommendations are due 30 days from the issuance date of this notice. All reply comments must be filed with the Commission within 45 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, and recommendations using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–13806–004.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The Brooklyn Dam Hydroelectric Project would consist of: (1) An existing 163-foot-long and 14-foot-high dam that includes: (a) A 113-foot-long spillway with a crest elevation 878.69 feet National Geodetic Vertical Datum of 1929 (NGVD29); (b) 2.50-foot-high flashboards with a crest elevation 881.23 feet NGVD29; and (c) a 50-foot-long floodgate structure with four 6.9-foot-wide, 10-foot-high floodgates; (2) an existing 100-foot-long, 45-foot-wide forebay with three 15.2-foot-wide, 15.5-foot-high trashracks with 1.0-inch open bar spacing; (3) an existing 40-foot-long, 15.78-foot-high tailrace training wall; (4) an existing 9-foot-wide, 9-foot-high side waste gate; (5) an existing 26-acre impoundment having a gross storage capacity of 52-acre-feet at elevation 881.23 feet NGVD29; (6) an existing 45-foot-long, 48-foot-wide, and 23-foot-high brick and concrete powerhouse that would contain two proposed 300-kilowatt (kW), Kaplan turbine-generating units for a total installed capacity of 600 kW; (7) an existing 48-foot-long, 45-foot-wide tailrace; (8) a proposed 400-foot-long 35.4-kilovolt

above-ground transmission line; (9) three proposed single phased transformers; and (10) appurtenant facilities. On average, the project would generate approximately 2,800 megawatt-hours annually. The applicant proposes to remove a non-operating sluice gate on the spillway, rehabilitate the powerhouse, and operate the project in a run-of-river mode.

m. Due to the project works already existing and the limited scope of proposed rehabilitation of the project site described above, the applicant's close coordination with federal and state agencies during the preparation of the application, completed studies during pre-filing consultation, and agency recommended preliminary terms and conditions, we intend to waive scoping and expedite the exemption process. Based on a review of the application, resource agency consultation letters including the preliminary 30(c) terms and conditions, and comments filed to date, Commission staff intends to prepare a single environmental assessment (EA). Commission staff determined that the issues that need to be addressed in its EA have been adequately identified during the pre-filing period, which included a public meeting and site visit, and no new issues are likely to be identified through additional scoping. The EA will consider assessing the potential effects of project construction and operation on aquatic, terrestrial, threatened and endangered species, recreation and land use, aesthetic, and cultural and historic resources.

n. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' ''COMPETING APPLICATION,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' or ''TERMS AND CONDITIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

p. *Procedural Schedule:* The application will be processed according to the following procedural schedule. Revisions to the schedule may be made as appropriate.

MILESTONE: Notice of the availability of the EA.

TARGET DATE: October 1, 2015.

Dated: April 23, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–10220 Filed 4–30–15; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 14628–001]**

### Minneapolis Leased Housing Associates IV, Limited Partnership; Notice of Application and Applicant-Prepared EA Accepted for Filing, Soliciting Motions To Intervene and Protests, and Soliciting Comments, and Final Terms and Conditions, Recommendations, and Prescriptions

Take notice that the following hydroelectric application and applicant-prepared environmental assessment has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Minor License.

b. *Project No.:* 14628–001.

c. *Date filed:* March 20, 2015.

d. *Applicant:* Minneapolis Leased Housing Associates IV, Limited Partnership (Minneapolis Housing Associates).

e. *Name of Project:* A-Mill Artist Lofts Hydroelectric Project (A-Mill Project).

f. *Location:* On the Mississippi River, in the City of Minneapolis, Hennepin County, Minnesota. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Owen Metz, 2905 Northwest Blvd., Suite 150, Plymouth, MN 55441; (763) 354–5618; email *ometz@dominiuminc.com*.

i. *FERC Contact:* Shana Murray at (202) 502–8333; or email at *shana.murray@ferc.gov*.

j. Deadline for filing motions to intervene and protests, comments, and final terms and conditions, recommendations, and prescriptions: 30 days from the issuance date of this notice; reply comments are due 45 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests, comments, and final terms and conditions, recommendations, and prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters,

without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14628–001.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing.

l. The A-Mill Project consists of: (1) Removal of an existing concrete bulkhead blocking the existing intake structure; (2) an existing headrace tunnel rehabilitated and sleeved with a new 616-foot-long, 5-foot-diameter steel penstock; (3) a new vertical steel pipe installed in the existing downstream drop-shaft; (4) a new 600-kilowatt turbine generator; (5) a new 6-foot-wide by 4-foot-tall concrete outlet structure at the existing downstream tailrace; and (6) appurtenant facilities. The average annual generation is estimated to be 3,400 megawatt-hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' ''COMPETING APPLICATION,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Dated: April 24, 2015.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2015–10221 Filed 4–30–15; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC15–128–000.
*Applicants:* American Transmission Company LLC.
*Description:* Application for Authority to Acquire Transmission Facilities of American Transmission Company LLC.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5164.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* EC15–129–000.
*Applicants:* 8point3 Energy Partners LP, Solar Star California XIII, LLC.
*Description:* Application for Authorization Under Section 203 of the Federal Power Act of 8point3 Energy Partners LP and Solar Star California XIII, LLC.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5254.
*Comments Due:* 5 p.m. ET 5/15/15.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER12–1739–001; ER11–2765–001; ER12–2310–003.
*Applicants:* Bethel Wind Energy LLC, Elk Wind Energy LLC, Zephyr Wind, LLC.
*Description*: Notice of Non-Material Change in Status of the Black Rock MBR Affiliates.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5237.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER13–1864–002.
*Applicants:* Southwest Power Pool, Inc.
*Description:* Compliance filing per 35: SPP–MISO JOA Sec 8.1.2 Market-to-Market Compliance Filing in Docket ER13–1864 to be effective 3/1/2015.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5263.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–760–001.
*Applicants:* Western Antelope Blue Sky Ranch A LLC.
*Description:* Supplement to December 30, 2014, February 19, 2015 and April 16, 2015 Western Antelope Blue Sky Ranch A LLC tariff filings.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5242.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–762–001.
*Applicants:* Sierra Solar Greenworks LLC.
*Description:* Supplement to December 30, 2014, February 19, 2015 and April 16, 2015 Sierra Solar Greenworks LLC tariff filings.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5238.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–978–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2738 Compliance ATC–WPSC PSA to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5167.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–979–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2739 Compliance ATC–UPPCo PSA to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5170.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–981–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2741 Compliance ATC–WEPC PSA to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5173.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–982–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2742 Compliance ATC–WPL FCA_Enbridge to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5175.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–983–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2743 Compliance ATC–WPL PCA (Didion) to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5176.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–984–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2744 Compliance ATC–WPL PCA_Dickinson to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5180.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–985–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2745 Compliance ATC–WPL PSA to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5186.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–986–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2746 Compliance ATC–MGE PCA to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5187.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–987–001.
*Applicants:* Midcontinent Independent System Operator, Inc.
*Description:* Compliance filing per 35: 2015–04–24_SA 2747 Compliance ATC–MGE PSA to be effective N/A.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5192.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–1447–001.
*Applicants:* Mid-Georgia Cogen L.P.
*Description:* Tariff Amendment per 35.17(b): Supplement to MBR Application to be effective 6/3/2015.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5152.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–1559–000.
*Applicants:* PJM Interconnection, L.L.C.
*Description:* Section 205(d) rate filing per 35.13(a)(2)(iii): Second Revised Service Agreement No. 2367 (Z1–088) to be effective 3/25/2015.
*Filed Date:* 4/23/15.
*Accession Number:* 20150423–5249.
*Comments Due:* 5 p.m. ET 5/14/15.

*Docket Numbers:* ER15–1560–000.
*Applicants:* Nevada Power Company.
*Description:* Section 205(d) rate filing per 35.13(a)(2)(iii): OATT Revisions to Attachment N to be effective 6/22/2015.
*Filed Date:* 4/23/15.
*Accession Number:* 20150423–5250.
*Comments Due:* 5 p.m. ET 5/14/15.

*Docket Numbers:* ER15–1561–000.
*Applicants:* Puget Sound Energy, Inc.
*Description:* Tariff Withdrawal per 35.15: Blaine TX SA No. 491 (Cancellation of Original) to be effective 4/24/2015.
*Filed Date:* 4/23/15.
*Accession Number:* 20150423–5251.
*Comments Due:* 5 p.m. ET 5/14/15.

*Docket Numbers:* ER15–1562–000.
*Applicants:* PJM Interconnection, L.L.C.
*Description:* Section 205(d) rate filing per 35.13(a)(2)(iii): PPL ISAs NQ112–126 to be effective 12/31/9998.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5067.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–1563–000.
*Applicants:* Alabama Power Company.
*Description:* Section 205(d) rate filing per 35.13(a)(2)(iii): PowerSouth NITSA Amendment Filing (to upgrade Ft. Mitchell Delivery Point) to be effective 3/30/2015.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5127.
*Comments Due:* 5 p.m. ET 5/15/15.

*Docket Numbers:* ER15–1564–000.
*Applicants:* Town Square Energy, LLC.
*Description:* Section 205(d) rate filing per 35.13(a)(2)(iii): Notice of Succession to be effective 4/2/2015.
*Filed Date:* 4/24/15.
*Accession Number:* 20150424–5265.
*Comments Due:* 5 p.m. ET 5/15/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 24, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015–10144 Filed 4–30–15; 8:45 am]

BILLING CODE 6717–01–P

**DEPARTMENT OF ENERGY**

**Western Area Power Administration**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

## Notice of Availability for Upper Great Plains Wind Energy Final Programmatic Environmental Impact Statement (DOE/EIS–0408)

**AGENCY:** Western Area Power Administration, DOE, and U.S. Fish and Wildlife Service, DOI.

**ACTION:** Notice of Availability.

**SUMMARY:** The Western Area Power Administration (Western) and the U.S. Fish and Wildlife Service (Service), joint lead agencies, announce the availability of the Upper Great Plains Wind Energy Final Programmatic Environmental Impact Statement (Final PEIS) (DOE/EIS–0408). The Final PEIS evaluates issues and environmental impacts associated with wind energy development within Western's Upper Great Plains Customer Service Region (UGP Region) and upon the Service's landscape-level grassland and wetland easements. The area covered by the PEIS encompasses all or parts of the states of Iowa, Minnesota, Montana, Nebraska, North Dakota, and South Dakota that fall within the UGP Region boundaries. In response to an increase in wind energy development, Western and the Service have interests in streamlining their procedures for conducting environmental reviews of wind energy applications by implementing standardized evaluation procedures and identifying measures to address potential environmental impacts associated with wind energy projects in the UGP Region. The U.S. Department of the Interior, Bureau of Reclamation (Reclamation) and Bureau of Indian Affairs (BIA), and the U.S. Department of Agriculture, Rural Utility Services (RUS), have participated as cooperating agencies. The Final PEIS and related project information is available on the project Web site at *http://plainswindeis.anl.gov.*

**DATES:** The Final PEIS will be publically available for at least 30 days before either agency makes its decision and issues its separate Record of Decision. The 30 days begin when the Environmental Protection Agency files its Notice of Availability (NOA) in the **Federal Register**, which should be concurrent with the publication of this NOA by the joint lead agencies. Both agencies will publish their Records of Decision in the **Federal Register**, once issued.

**ADDRESSES:** Western and the Service encourage interested parties to access the Final PEIS on the project Web site at *http://plainswindeis.anl.gov.* Copies of the Final PEIS on CD can be obtained from Mark Wieringa, NEPA Document Manager, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213, telephone (800) 336–7288, facsimile (720) 962–7269, email *wieringa@wapa.gov.*

**FOR FURTHER INFORMATION CONTACT:** For information on Western's proposed programmatic environmental evaluation procedures for wind energy project interconnections, and general information about interconnections with Western's transmission system, contact Matt Marsh, Regional Environmental Manager, Upper Great Plains Customer Service Region, Western Area Power Administration, P.O. Box 35800, Billings, MT 59107–5800, telephone (406) 255–2810, facsimile (406) 255–2900, email *mmarsh@wapa.gov.* For information on the PEIS process, or to receive a copy of the Final PEIS, contact Mark Wieringa, NEPA Document Manager, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213, telephone (800) 336–7288, facsimile (720) 962–7269, email *wieringa@wapa.gov.*

For information on the Service's participation in the PEIS, contact Dave Azure, U.S. Fish and Wildlife Service, Arrowwood National Wildlife Refuge, 7780 10th Street SE., Pingree, ND 58476, telephone (701) 285–3341 ext. 107, facsimile (701) 285–3350, email *Dave_Azure@fws.gov.*

For general information on the DOE NEPA process, please contact Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, telephone (202) 586–4600 or (800) 472–2756.

**SUPPLEMENTARY INFORMATION:** Western and the Service, joint lead agencies, announce the availability of the Upper Great Plains Wind Energy Final PEIS (DOE/EIS–0408). In response to an increase in wind energy development, Western and the Service have interests in streamlining their procedures for conducting environmental reviews of wind energy applications by implementing standardized evaluation procedures and identifying measures to address potential environmental impacts associated with wind energy projects in the UGP Region, which encompasses all or parts of the states of Iowa, Minnesota, Montana, Nebraska, North Dakota, and South Dakota. Since formalizing the process and procedures for environmental reviews would be Federal actions, Western and the Service prepared the PEIS in accordance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347), as amended, and the Council on Environmental Quality (CEQ) NEPA regulations (40 CFR parts 1500–1508). Western and the Service agreed to be joint lead agencies, as provided for under NEPA and CEQ regulations (40 CFR 1501.5(b)). Reclamation, BIA, and RUS have participated in the development of the PEIS as cooperating agencies.

Western and the Service have cooperatively prepared the PEIS to: (1) Assess the potential environmental impacts associated with wind energy projects within the UGP Region that may interconnect to Western's transmission system, or that may propose placement of project elements on grassland or wetland easements managed by the Service, and (2) evaluate how environmental impacts would differ under alternative sets of environmental evaluation procedures, best management practices, avoidance strategies, and mitigation measures that the agencies would request project developers to implement, as appropriate for specific wind energy projects.

The objective of the PEIS is to proactively strengthen and streamline the environmental review process by having already analyzed and addressed general environmental concerns while specifically providing for Endangered Species Act (ESA) compliance for wind development projects that incorporate design elements to reduce impacts. The PEIS analyzes, to the extent practicable, the impacts resulting from development of wind energy projects and the effectiveness of best management practices, avoidance of sensitive areas, and mitigation measures in reducing potential impacts. Impacts and mitigation have been analyzed for each environmental resource, and all components of wind energy projects have been addressed, including turbines, transformers, collector lines, overhead lines, access roads, substation installations, and operational and maintenance activities. Many of the impacts resulting from constructing and operating these types of wind energy infrastructure are well known from existing wind energy generation developments. The environmental procedures and mitigation strategies developed have been structured to complement Western's Open Access Transmission Service Tariff, which also

includes environmental review provisions.

The PEIS collected and analyzed this information as it applies to wind energy development in the six states included in the UGP Region. Specifically, through the PEIS Western and the Service have:

1. Defined areas with a high potential for wind energy development near the UGP Region's transmission system in anticipation of future wind-generation interconnection requests.

2. Defined natural and human environment resources in areas with high wind energy development potential, including Native American lands, to support analyses of the environmental impacts and development of wind energy projects.

3. Identified standardized environmental evaluation procedures, avoidance areas, best management practices, and mitigation measures to be used by interconnection applicants for identifying and reducing wind energy development impacts of their projects on the natural and human environment.

4. Initiated a programmatic ESA Section 7 informal consultation for federally listed and proposed threatened and endangered species within the study area boundaries established for the PEIS that may be affected by future wind energy development.

5. Provided guidance for interconnection applicants that includes information about natural resources within areas with a high potential for wind development, requirements for subsequent site-specific environmental reviews, avoidance areas, and appropriate best management practices and mitigation measures to address adverse environmental impacts related to wind projects and associated transmission system enhancements.

The Service maintains a grassland and wetland easement program to support and enhance waterfowl populations in the Prairie Pothole Region. The Service has developed a plan that will, in some circumstances, allow partial release of an easement for wind generation purposes, only with defined conditions and on a specified area, in exchange for additional easement acreage being conveyed to the Service. A streamlined approach for compliance with NEPA and ESA for future site-specific wind development projects would result from this PEIS, and would benefit both agencies.

Western and the Service are engaged in informal consultation under Section 7 of the ESA in support of the PEIS process. A Programmatic Biological Assessment has been prepared for listed and candidate species occurring in the UGP Region, and it is expected that the Service's Ecological Services Field Office will issue a letter of concurrence as a result of this consultation.

Separate Records of Decision addressing each agency's Federal actions will be issued by Western and the Service not sooner than 30 days after distribution of the Final PEIS and the date of the Environmental Protection Agency's weekly **Federal Register** notice listing the availability of the EIS.

Dated: April 21, 2015.

**Mark A. Gabriel,**

*Administrator, Western Area Power Administration.*

Dated: January 28, 2015.

**Matt Hogan,**

*Deputy Regional Director, Mountain-Prairie Region, U.S. Fish and Wildlife Service.*

[FR Doc. 2015–10237 Filed 4–30–15; 8:45 am]

BILLING CODE 6450–01–P

## ENVIRONMENTAL PROTECTION AGENCY

**[ER–FRL–9020–7]**

## Environmental Impact Statements; Notice of Availability

*Responsible Agency:* Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/*.

Weekly receipt of Environmental Impact Statements

Filed 04/20/2015 Through 04/24/2015

Pursuant to 40 CFR 1506.9.

### Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html*.

*EIS No. 20150117, Draft EIS, NPS, HI,* Hawaii Volcanoes National Park Draft General Management Plan and Wilderness Study, Comment Period Ends: 06/30/2015, Contact: Cindy Orlando 808–985–6026.

*EIS No. 20150118, Draft Supplement, USACE, CA,* Mather Specific Plan, Comment Period Ends: 06/15/2015, Contact: Mary Pakenham-Walsh 916–557–7718.

*EIS No. 20150119, Final EIS, OSM, NM,* Four Corners Power Plant and Navajo Mine Energy Project, Review Period Ends: 06/01/2015, Contact: Mychal Yellowman 303–293–5049.

*EIS No. 20150120, Final EIS, WAPA, USFWS, 00,* PROGRAMMATIC—Upper Great Plains Wind Energy Project, Review Period Ends: 06/01/2015, Contact: Mark Wieringa 720–962–7448.

The U.S. Department of Energy's Western Area Power Administration and the U.S. Department of the Interior's Fish and Wildlife Service are joint lead agencies for the above project.

*EIS No. 20150121, Final EIS, BLM, WY,* TransWest Express Transmission Project, Review Period Ends: 06/01/2015, Contact: Sharon Knowlton 307–775–6124.

*EIS No. 20150122, Final EIS, APHIS, OR,* ADOPTION—Double-crested Cormorant Management Plan to Reduce Predation of Juvenile Salmonids in the Columbia River Estuary, Contact: Kevin Christensen 503–326–2346.

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has adopted the U.S. Army Corps of Engineers FEIS #20150122, filed with the U.S. EPA on 2/25/2015. APHIS was a cooperating agency on this project, therefore, recirculation of the document is not necessary under section 1506.3(c) of CEQ Regulations.

Dated: April 28, 2015.

**Cliff Rader,**

*Director, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 2015–10218 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OAR–2003–0034; FRL–9927–08–OEI]**

## Proposed Information Collection Request; Comment Request; Voluntary Aluminum Industrial Partnership (VAIP) (Renewal)

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), Voluntary Aluminum Industrial Partnership (VAIP) (Renewal)—EPA ICR No. 1867.05, OMB Control No. 2060–0411—to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through June 30, 2015. 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 June 30, 2015.

**ADDRESSES:** Submit your comments, referencing the Docket ID number provided above, 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:** Sally Rand, Climate Change Division, Office of Atmospheric Programs (6207J), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–343–9739; fax number: 202–343–2202; email address: *rand.sally@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

*Abstract:* EPA's Voluntary Aluminum Industrial Partnership (VAIP) was initiated in 1995 and is an important voluntary program contributing to the overall reduction in emissions of greenhouse gases. This program focuses on reducing direct greenhouse gas emissions including perfluorocarbon (PFC) and carbon dioxide ($CO_2$) emissions from the production of primary aluminum. Six of the seven U.S. producers of primary aluminum participate in this program. PFCs are very potent greenhouse gases with global warming potentials several thousand times that of carbon dioxide, and they persist in the atmosphere for thousands of years. $CO_2$ is emitted from consumption of the carbon anode. The Partnership effectively promotes the adoption of emission reduction technologies and practices associated with decreasing the frequency and duration of anode effects. Participants voluntarily agree to designate a VAIP liaison, and to undertake and share information on technically feasible and cost-effective actions to reduce PFC and direct $CO_2$ emissions. The information contained in the annual reports of VAIP members is used by EPA to assess the success of the program in achieving its goals and to advance Partner efforts to reduce greenhouse gas emissions.

*Respondents/affected entities:* Producers of primary aluminum.

*Respondent's obligation to respond:* Voluntary.

*Estimated number of respondents:* 6 (total).

*Frequency of response:* Voluntary.

*Total estimated burden:* 240 hours (per year). Burden is defined at 5 CFR 1320.03(b).

*Total estimated cost:* $22,668 (per year), includes no annualized capital or operation & maintenance costs.

**Courtney Kerwin,**

*Acting Director, Collection Strategies Division.*

[FR Doc. 2015–10124 Filed 4–30–15; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9927–07–Region–10]**

## Proposed Issuance of NPDES General Permit for Tribal Marine Net Pen Enhancement Facilities in Washington State (Permit Number WAG132000)

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

**ACTION:** Notice of proposed issuance of NPDES General Permit and request for public comment.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 10 proposes to issue a National Pollutant Discharge Elimination System (NPDES) General Permit for Tribal Marine Net Pen Enhancement Facilities in Washington State (General Permit). As proposed, the General Permit authorizes discharges to Waters of the U.S. within the State of Washington. The draft General Permit contains effluent limitations, along with administrative reporting and monitoring requirements, as well as standard conditions, prohibitions, and management practices. A fact sheet is available that explains the draft General Permit in detail. Section 401 of the Clean Water Act, 33 U.S.C. 1341, requires EPA to seek a certification from the State of Washington that the conditions of the general permit are stringent enough to comply with State water quality standards. The Washington Department of Ecology (Ecology) has provided a draft certification that the draft General Permit complies with the State of Washington Water Quality Standards. EPA intends to seek a final certification from Ecology prior to issuing the General Permit. This is also notice of the draft § 401 certification provided by Ecology. Persons wishing to comment on the draft State certification should send written comments to Mr. Bill Moore; Water Quality Program, Washington Department of Ecology, P.O. Box 47696, Olympia, Washington 98504–7696 or via email to *bmoo461@ecy.wa.gov.*

**DATES:** The public comment period for the draft General Permit will be from the date of publication of this Notice until June 30, 2015. Comments must be received or postmarked by no later than midnight Pacific Standard Time on June 30, 2015. All comments related to the draft General Permit and Fact Sheet received by EPA Region 10 by the comment deadline will be considered prior to issuing the General Permit.

*Submitting Comments:* You may submit comments by any of the

following methods. All comments must include the name, address, and telephone number of the commenter.

*Mail:* Send paper comments to Ms. Catherine Gockel, Office of Water and Watersheds; USEPA Region 10; 1200 6th Ave., Suite 900, OWW–191; Seattle, Washington 98101.

*Email:* Send electronic comments to *catherin.gockel@epa.gov.* Make sure to write ''Comments on the Draft Tribal Marine Net Pen Enhancement Facilities General Permit'' in the subject line.

*Fax:* Fax comments to the attention of Catherine Gockel at (206) 553–0325.

*Hand Delivery/Courier:* Deliver comments to Catherine Gockel, EPA Region 10, Office of Water and Watersheds, Mail Stop OWW–191, 1200 6th Avenue, Suite 900, Seattle, WA 98101–3140. Call (206) 553–0523 before delivery to verify business hours.

*Viewing and/or Obtaining Copies of Documents.* A copy of the draft General Permit and the Fact Sheet, which explains the proposal in detail, may be obtained by contacting EPA at 1 (800) 424–4372. Copies of the documents are also available for viewing and downloading at: *www.epa.gov/r10earth/waterpermits.htm.*

Requests may also be made to Audrey Washington at (206) 553–0523 or *washington.audrey@epa.gov.*

*Public Hearing:* Persons wishing to request a public hearing should submit their written request by June 30, 2015 stating the nature of the issues to be raised as well as the requester's name, address, and telephone number to Catherine Gockel at the address above. If a public hearing is scheduled, notice will be published in the **Federal Register**. Notice will also be posted on the Region 10 Web site, and will be mailed to all interested persons receiving letters of the availability of the Draft General Permit.

**FOR FURTHER INFORMATION CONTACT:** Additional information can be obtained by contacting Catherine Gockel, Office of Water and Watersheds, U.S. Environmental Protection Agency, Region 10. Contact information is included above in the ''Submitting Comments'' Section.

## Other Legal Requirements

*Endangered Species Act [16 U.S.C. 1531 et al.].* Section 7 of the Endangered Species Act (ESA) requires Federal agencies to consult with NOAA Fisheries (NMFS) and the U.S. Fish and Wildlife Service (USFWS) (the Services) if their actions have the potential to either beneficially or adversely affect any threatened or endangered species. EPA has analyzed the discharges proposed to be authorized by the draft General Permit, and their potential to adversely affect any of the threatened or endangered species or their designated critical habitat areas in the vicinity of the discharges. Based on this analysis, EPA has determined that the issuance of this permit will have no effect to any threatened or endangered species in the vicinity of the discharge. Therefore, ESA consultation is not required.

*National Environmental Policy Act (NEPA) [42 U.S.C. 4321 et seq.] and Other Federal Requirements.* Regulations at 40 CFR 122.49, list the federal laws that may apply to the issuance of permits *i.e.,* ESA, National Historic Preservation Act, the Coastal Zone Act Reauthorization Amendments (CZARA), NEPA, and Executive Orders, among others. The NEPA compliance program requires analysis of information regarding potential impacts, development and analysis of options to avoid or minimize impacts; and development and analysis of measures to mitigate adverse impacts. EPA determined that no Environmental Assessments (EAs) or Environmental Impact Statements (EISs) are required under NEPA. EPA also determined that CZARA does not apply.

*Essential Fish Habitat (EFH).* The Magnuson-Stevens Fishery Management and Conservation Act requires EPA to consult with NOAA–NMFS when a proposed discharge has the potential to adversely affect a designated EFH. The EFH regulations define an adverse effect as ''any impact which reduces quality and/or quantity of EFH . . . [and] may include direct (*e.g.* contamination or physical disruption), indirect (*e.g.* loss of prey, reduction in species' fecundity), site-specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions.'' NMFS may recommend measures for attachment to the federal action to protect EFH; however, such recommendations are advisory, and not prescriptive in nature. EPA has evaluated the Draft General Permit and has made the determination that issuance of the General Permit will have no effect on EFH.

*Executive Order 12866:* The Office of Management and Budget (OMB) exempts this action from the review requirements of Executive Order 12866 pursuant to Section 6 of that order.

*Economic Impact [Executive Order 12291]:* The EPA has reviewed the effect of Executive Order 12291 on this Draft General Permit and has determined that it is not a major rule pursuant to that Order.

*Paperwork Reduction Act [44 U.S.C. 3501 et seq.]* The EPA has reviewed the requirements imposed on regulated facilities in the Draft General Permit and finds them consistent with the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

*Regulatory Flexibility Act [5 U.S.C. 601 et seq.]* The Regulatory Flexibility Act (RFA) requires that EPA prepare an initial regulatory flexibility analysis for rules subject to the requirements of the Administrative Procedures Act [APA, 5 U.S.C. 553] that have a significant impact on a substantial number of small entities. However, EPA has concluded that NPDES General Permits are not rulemakings under the APA, and thus not subject to APA rulemaking requirements or the RFA.

*Unfunded Mandates Reform Act:* Section 201 of the Unfunded Mandates Reform Act (UMRA), Public Law 104–4, generally requires Federal agencies to assess the effects of their regulatory actions (defined to be the same as rules subject to the RFA) on tribal, state, and local governments, and the private sector. However, General NPDES Permits are not rules subject to the requirements of the APA, and are, therefore, not subject to the UMRA.

**Authority:** This action is taken under the authority of Section 402 of the Clean Water Act as amended, 42 U.S.C. 1342. I hereby provide public notice of the Draft General Permit for Tribal Marine Net Pen Enhancement Facilities in Washington State in accordance with 40 CFR 124.10.

Dated: April 23, 2015.

**Daniel D. Opalski,**

*Director, Office of Water and Watersheds, Region 10.*

[FR Doc. 2015–10243 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OAR–2011–0891; FRL–9927–06–OEI]**

## Proposed Information Collection Request; Comment Request; Recordkeeping and Periodic Reporting of the Production, Import, Export, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (Renewal)

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Recordkeeping and Periodic Reporting of the Production, Import, Export, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (Renewal)'' (EPA ICR No.

1432.31, OMB Control No. 2060–0170 to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through June 30, 2015. 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 June 30, 2015.

**ADDRESSES:** Submit your comments, referencing the Docket ID No. listed above, 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:** Staci Gatica, Stratospheric Protection Division, Office of Atmospheric Programs (6205J), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 343–9469; fax number: (202) 343–2338; email address: *gatica.staci@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

*Abstract:* This ICR authorizes the recordkeeping and reporting requirements established in the regulations stated in 40 CFR part 82, subpart A and as required by the United States' commitments under *The Montreal Protocol on Substances that Deplete the Ozone Layer* (Protocol). This information collection allows EPA to monitor the United States' compliance with the Protocol and Title VI of the Clean Air Act Amendments of 1990 (CAA).

Under its Protocol commitments, the United States is obligated to cease production and import of Class I controlled substances excluding chlorofluorocarbons (CFCs) that are subject to essential use exemptions, methyl bromide that is subject to critical use exemptions or exemptions for quarantine and preshipment uses, previously used material, and material that will be transformed, destroyed, or exported to developing countries. The Protocol also establishes limits and reduction schedules leading to the eventual phaseout of Class II controlled substances with similar exemptions beyond the phaseout. The CAA has its own limits on production and consumption of controlled substances that EPA must adhere to and enforce.

Under 40 CFR 82.13, producers, importers, exporters, and distributors of Class I ozone-depleting substances (ODS) must meet quarterly, annual, and/or transactional recordkeeping and reporting requirements.

The reporting and recordkeeping requirements for Class I ODS will enable EPA to: (1) Ensure compliance with the restrictions on production, import, and export of Class I controlled substances; (2) allow exempted production and import for certain uses and the consequent tracking of that production and import; (3) address industry and Federal concerns regarding the illegal import of mislabeled used controlled substances; (4) satisfy the United States' obligations to report data under Article 7 of the Montreal Protocol; (5) fulfill statutory obligations under Section 603(b) of the CAA for reporting and monitoring; (6) provide information to report to the U.S. Congress on the production, use, and consumption of Class I controlled substances as statutorily required in Section 603(d) of Title VI of the CAA.

The reported data will enable EPA to maintain compliance with the Protocol requirements for annual data submission on the production of ODS and analyze technical use data to ensure that exemptions are used in accordance with requirements included in the annual authorization rulemakings.

*Respondents/affected entities:* Chemical Producers, Importers, and Exporters (CFCs); Research and Development (Laboratories); and MeBr Producers, Importers, Exporters, Distributors, and Applicators.

*Respondent's obligation to respond:* Mandatory.

*Estimated number of respondents:* 1143 (total).

*Frequency of response:* Quarterly, annually, occasionally.

*Total estimated burden:* 2583 hours (per year). Burden is defined at 5 CFR 1320.03(b).

*Total estimated cost:* $277,085 (per year), includes $5,535 annualized capital or operation & maintenance costs.

**Courtney Kerwin,**

*Acting Director, Collections Strategies Division.*

[FR Doc. 2015–10123 Filed 4–30–15; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OPPT–2013–0677; FRL–9926–44]**

## Receipt of Test Data Under the Toxic Substances Control Act

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

**ACTION:** Notice; correction.

**SUMMARY:** EPA issued a notice in the **Federal Register** of April 14, 2015, announcing its receipt of test data submitted pursuant to a test rule issued by EPA under the Toxic Substances Control Act (TSCA). As required by TSCA, this document identifies each chemical substance and/or mixture for

which test data have been received; the uses or intended uses of such chemical substance and/or mixture; and describes the nature of the test data received. Under Unit IV.A.3. and B.3. Test Data Received; information was inadvertently omitted, and this document corrects the omissions.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Kathy Calvo, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8089; email address: *calvo.kathy@epa.gov.*

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

**SUPPLEMENTARY INFORMATION:**

**What does this correction do?**

FR Doc. 2015–08588, published in the **Federal Register** of April 14, 2015, (80 FR 19982) (FRL–9925–21) is corrected to read as follows:

1. On page 19982 under Unit IV. Test Data Received A.3., after the sentence: ''*Aquatic Toxicity.* The docket ID number assigned to this data is EPA–HQ–OPPT–2007–0531–0832.'' Add the sentence:

*Ready Biodegradation.* The docket ID number assigned to this data is EPA–HQ–OPPT–2007–0531.

2. On page 19982 under Unit IV. Test Data Received B.3., is corrected to read as follows:

*Aquatic Toxicity (Algae).* The docket ID number assigned to this data is EPA–HQ–OPPT–2009–0112.

*Mammalian Toxicity. Repeat Dose Reproductive/Developmental Study with Screening Test.* The docket ID number assigned to this data is EPA–HQ–OPPT–2009–0112.

**Authority:** 15 U.S.C. 2601 *et seq.*

Dated: April 23, 2015.

**Maria J. Doa,**

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

[FR Doc. 2015–10142 Filed 4–30–15; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL COMMUNICATIONS COMMISSION

**[OMB 3060–1180]**

## Information Collection Being Reviewed by the Federal Communications Commission

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written PRA comments should be submitted on or before June 30, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

**SUPPLEMENTARY INFORMATION:**

*OMB Control Number:* 3060–1180.

*Title:* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions.

*Form Number:* N/A.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit entities, state, local, or tribal government and not for profit institutions.

*Number of Respondents:* 378 respondents; 378 responses.

*Estimated Time per Response:* 0.5 to 2 hours.

*Frequency of Response:* One-time and on occasion reporting requirements, twice within 12 years reporting requirement, 6, 10 and 12-years reporting requirements and third party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for these collections are contained in 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 325(b), 332, 336(f), 338, 339, 340, 399b, 403, 534, 535, 1404, 1452, and 1454 of the Communications Act of 1934.

*Total Annual Burden:* 581 hours.

*Total Annual Cost:* No cost.

*Privacy Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* There is no need for confidentiality with this collection of information.

*Needs and Uses:* The FCC adopted the Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions Report and Order, FCC 14–50, on May 15, 2014, published at 79 FR 48442 (Aug. 15, 2014). The Commission seeks approval from the Office of Management and Budget (OMB) for some of the information collection requirements contained in FCC 14–50. The Commission will use the information to ensure compliance with required filings of notifications, certifications, license renewals, license cancelations, and license modifications. Also, such information will be used to minimize interference and to determine compliance with Commission's rules.

The following is a description of the information collection requirements for which the Commission seeks OMB approval:

Section 27.14(k) requires 600 MHz licensees to demonstrate compliance with performance requirements by filing a construction notification with the Commission, within 15 days of the applicable benchmark.

Section 27.14(t)(6) requires 600 MHz licensees to make a renewal showing as a condition of each renewal. The showing must include a detailed description of the applicant's provision

of service during the entire license period and address: (i) The level and quality of service provided by the applicant (including the population served, the area served, the number of subscribers, the services offered); (ii) the date service commenced, whether service was ever interrupted, and the duration of any interruption or outage; (iii) the extent to which service is provided to rural areas; (iv) the extent to which service is provided to qualifying tribal land as defined in 47 CFR 1.2110(f)(3)(i); and (v) any other factors associated with the level of service to the public.

Section 27.17(c) requires 600 MHz licensees to notify the Commission within 10 days of discontinuance if they permanently discontinue service by filing FCC Form 601 or 605 and requesting license cancellation.

Section 27.19(b) requires 600 MHz licensees with base and fixed stations in the 600 MHz downlink band within 25 kilometers of Very Long Baseline Array (VLBA) observatories to coordinate with the National Science Foundation (NSF) prior to commencing operations.

Section 27.19(c) requires 600 MHz licensees that intend to operate base and fixed stations in the 600 MHz downlink band in locations near the Radio Astronomy Observatory site located in Green Bank, Pocahontas County, West Virginia, or near the Arecibo Observatory in Puerto Rico, to comply with the provisions in 47 CFR 1.924.

Section 74.602(h)(5)(ii) requires 600 MHz licensees to notify the licensee of a studio-transmitter link (TV STL), TV relay station, or TV translator relay station of their intent to commence wireless operations and the likelihood of harmful interference from the TV STL, TV relay station, or TV translator relay station to those operations within the wireless licensee's licensed geographic service area. The notification is to be in the form of a letter, via certified mail, return receipt requested and must be sent not less than 30 days in advance of approximate date of commencement of operations.

Section 74.602(h)(5)(iii) requires all TV STL, TV relay station and TV translator relay station licensees to modify or cancel their authorizations and vacate the 600 MHz band no later than the end of the post-auction transition period as defined in 47 CFR 27.4.

These rules which contain information collection requirements are designed to provide for flexible use of this spectrum by allowing licensees to choose their type of service offerings, to encourage innovation and investment in mobile broadband use in this spectrum, and to provide a stable regulatory environment in which broadband deployment would be able to develop through the application of standard terrestrial wireless rules. Without this information, the Commission would not be able to carry out its statutory responsibilities.

Federal Communications Commission.

**Gloria J. Miles,**

*Federal Liaison Officer, Office of the Managing Director.*

[FR Doc. 2015–10206 Filed 4–30–15; 8:45 am]

**BILLING CODE 6712–01–P**

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## FEDERAL COMMUNICATIONS COMMISSION

**[OMB 3060–1162]**

### Information Collection Being Reviewed by the Federal Communications Commission

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written PRA comments should be submitted on or before June 30, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

**SUPPLEMENTARY INFORMATION:**

*OMB Control Number:* 3060–1162.

*Title:* Closed Captioning of Video Programming Delivered Using Internet Protocol, and Apparatus Closed Caption Requirements.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Individuals or households; Business or other for-profit entities; Not-for-profit institutions.

*Number of Respondents and Responses:* 1,322 respondents; 3,666 responses.

*Estimated Time per Response:* 0.084 to 10 hours.

*Frequency of Response:* One time and on occasion reporting requirements; Recordkeeping requirement; Third-party disclosure requirement.

*Obligation to Respond:* Mandatory and required to obtain or retain benefits. The statutory authority for this information collection is contained in the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 124 Stat. 2751, and Sections 4(i), 4(j), 303, 330(b), 713, and 716 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 303, 330(b), 613, and 617.

*Total Annual Burden:* 10,062 hours.

*Total Annual Cost:* $95,700.

*Privacy Act Impact Assessment:* Yes. As required by OMB Memorandum M–03–22 (September 26, 2003), the FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007, that gives a full and complete explanation of how the FCC collects, stores, maintains, safeguards, and destroys the PII covered by these information collection requirements. The PIA may be reviewed at: *http://www.fcc.gov/omd/privacyact/Privacy_Impact_Assessment.html.*

*Nature and Extent of Confidentiality:* Some assurances of confidentiality are being provided to the respondents. Parties filing petitions for exemption based on economic burden, requests for Commission determinations of technical feasibility and achievability, requests for purpose-based waivers, or responses to complaints alleging violations of the

Commission's rules may seek confidential treatment of information they provide pursuant to the Commission's existing confidentiality rules.

The Commission is not requesting that individuals who file complaints alleging violations of our rules (complainants) submit confidential information (*e.g.,* credit card numbers, social security numbers, or personal financial information) to us. We request that complainants submit their names, addresses, and other contact information, which enables us to process complaints. Any use of this information is covered under the routine uses listed in the Commission's SORN, FCC/CGB–1, ''Informal Complaints, Inquiries, and Requests for Dispute Assistance.''

The PIA that the FCC completed on June 28, 2007 gives a full and complete explanation of how the FCC collects, stores, maintains, safeguards, and destroys PII, as required by OMB regulations and the Privacy Act, 5 U.S.C. 552a. The PIA may be viewed at: *http://www.fcc.gov/omd/privacyact/Privacy_Impact_Assessment.html.*

The Commission will update the PIA to cover the PII collected related to this information collection to incorporate various revisions to it as a result of revisions to the SORN and as required by OMB's Memorandum M–03–22 (September 26, 2003) and by the Privacy Act, 5 U.S.C. 552a.

*Needs and Uses:* The Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA) directed the Commission to revise its regulations to mandate closed captioning on IP-delivered video programming that was published or exhibited on television with captions after the effective date of the regulations. Accordingly, the Commission requires video programming owners (VPOs) to send program files to video programming distributors and providers (hereinafter VPDs) with required captions, and it requires VPDs to enable the rendering or pass through of all required captions to the end user. The CVAA also directed the Commission to revise its regulations to mandate that all apparatus designed to receive, play back, or record video programming be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, except that apparatus that use a picture screen that is 13 inches or smaller and recording devices must comply only if doing so is achievable. These rules are codified at 47 CFR 79.4 and 79.100–79.104.

*The information collection requirements consist of:*

(a) Mechanism for information about video programming subject to the IP closed captioning requirements.

Pursuant to 47 CFR 79.4(c)(1)(ii) and (c)(2)(ii) of the Commission's rules, VPOs and VPDs must agree upon a mechanism to make information available to VPDs about video programming that becomes subject to the requirements of 47 CFR 79.4 on an ongoing basis. VPDs must make a good faith effort to identify video programming that must be captioned when delivered using IP using the agreed upon mechanism.

For example, VPOs and VPDs may agree on a mechanism whereby the VPOs provide captions or certifications that captions are not required, and update those certifications and provide captions when captions later become required. A VPD may rely in good faith on a certification by a VPO that the programming need not be captioned: (1) If the certification includes a clear and concise explanation of why captions are not required; and (2) if the VPD is able to produce the certification to the Commission in the event of a complaint. VPOs may provide certifications for specific programming or a more general certification, for example, for all programming covered by a particular contract.

VPDs may seek Commission determinations that other proposed mechanisms provide adequate information for them to rely on in good faith by filing an informal request and providing sufficient information for the Commission to make such determinations.

(b) Contact information for the receipt and handling of written closed captioning complaints.

Pursuant to 47 CFR 79.4(c)(2)(iii), VPDs must make their contact information available to end users for the receipt and handling of written IP closed captioning complaints. The required contact information includes the name of a person with primary responsibility for IP captioning issues and who can ensure compliance with these rules, as well as the person's title or office, telephone number, fax number, postal mailing address, and email address. VPDs must keep this information current and update it within 10 business days of any change. The Commission expects that such contact information will be prominently displayed in a way that it is accessible to all end users. A general notice on the VPD's Web site with such contact information, if provided, must be provided in a location that is conspicuous to viewers.

(c) Petitions for exemption based on ''economic burden.''

Pursuant to 47 CFR 79.4(d), a VPO or VPD may petition the Commission for a full or partial exemption from the closed captioning requirements for IP-delivered video programming based upon a showing that they would be economically burdensome. Petitions for exemption must be supported with sufficient evidence to demonstrate economic burden (significant difficulty or expense). The Commission will consider four specific factors when determining economic burden and any other factors the petitioner deems relevant, along with any available alternatives that might constitute a reasonable substitute for the closed captioning requirements. Petitions and subsequent pleadings must be filed electronically.

The Commission will place such petitions on public notice. Comments or oppositions to the petition may be filed electronically within 30 days after release of the public notice of the petition, and must include a certification that the petitioner was served with a copy. The petitioner may reply to any comments or oppositions filed within 20 days after the close of the period for filing comments or oppositions, and replies must include a certification that the commenting or opposing party was served with a copy. Upon a finding of good cause, the Commission may lengthen or shorten any comment period and waive or establish other procedural requirements. Petitions and responsive pleadings must include a detailed, full showing, supported by affidavit, of any facts or considerations relied on.

(d) Complaints alleging violations of the closed captioning rules for IP-delivered video programming.

Pursuant to 47 CFR 79.4(e), a written complaint alleging a violation of the closed captioning rules for IP-delivered video programming may be filed with the Commission or with the VPD responsible for enabling the rendering or pass through of the closed captions for the video programming. Complaints must be filed within 60 days after the date the complainant experienced a problem with captioning. Such complaints should (but are not required to) include certain information.

If a complaint is filed first with the VPD, the VPD must respond in writing to the complainant within 30 days after receipt of a closed captioning compliant. If a VPD fails to respond timely, or the response does not satisfy the consumer, the complainant may re-

file the complaint with the Commission within 30 days after the time allotted for the VPD to respond. If a consumer re-files the complaint with the Commission (after filing with the VPD) and the complaint satisfies the requirements, the Commission will forward the complaint to the named VPD, and to any other VPD and/or VPO that Commission staff determines may be involved, who then must respond in writing to the Commission and the complainant within 30 days after receipt of the complaint from the Commission.

If a complaint is filed first with the Commission and the complaint satisfies the requirements, the Commission will forward the complaint to the named VPD and/or VPO, and to any other VPD and/or VPO that Commission staff determine may be involved, who must respond in writing to the Commission and the complainant within 30 days after receipt of the complaint from the Commission. In response to a complaint, a VPD and/or VPO must provide the Commission with sufficient records and documentation. The Commission will review all relevant information provided by the complainant and the subject VPDs and/or VPOs, as well as any additional information the Commission deems relevant from its files or public sources. The Commission may request additional information from any relevant entities when, in the estimation of Commission staff, such information is needed to investigate the complaint or adjudicate potential violation(s) of Commission rules. When the Commission requests additional information, parties to which such requests are addressed must provide the requested information in the manner and within the time period the Commission specifies.

(e) Requests for Commission determination of technical feasibility of apparatus closed caption requirements.

Pursuant to 47 CFR 79.103(a), as of January 1, 2014, all digital apparatus designed to receive or play back video programming that uses a picture screen of any size must be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, if *technically feasible.* If new apparatus or classes of apparatus for viewing video programming emerge on which it would not be technically feasible to include closed captioning, parties may raise that argument as a defense to a complaint or, alternatively, file a request under 47 CFR 1.41 for a Commission determination of technical feasibility before manufacturing or importing the product.

(f) Requests for Commission determination of achievability of apparatus closed caption requirements.

Pursuant to 47 CFR 79.103(a), as of January 1, 2014, all digital apparatus designed to receive or play back video programming that use a picture screen less than 13 inches in size must be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, only if doing so is *achievable.* In addition, pursuant to 47 CFR 79.104(a), as of January 1, 2014, all apparatus designed to record video programming must enable the rendering or the pass through of closed captions such that viewers are able to activate and de-activate the closed captions as the video programming is played back, only if doing so is *achievable.*

Manufacturers of such apparatus may petition the Commission, pursuant to 47 CFR 1.41, for a full or partial exemption from the closed captioning requirements before manufacturing or importing the apparatus or may assert as a response to a complaint that these requirements, in full or in part, are not achievable. Pursuant to 47 CFR 79.103(b)(3), such a petition or response must be supported with sufficient evidence to demonstrate that compliance is not achievable (meaning with reasonable effort or expense) and the Commission will consider four specific factors when making such determinations. In evaluating evidence offered to prove that compliance was not achievable, the Commission will be informed by the analysis in the *ACS Order.*

(g) Petitions for purpose-based waivers of apparatus closed caption requirements.

Manufacturers seeking certainty prior to the sale of a device may petition the Commission, pursuant to 47 CFR 79.104(b)(4), for a full or partial waiver of the closed captioning requirements based on one of the following provisions:

(i) The apparatus is primarily designed for activities other than receiving or playing back video programming transmitted simultaneously with sound; or

(ii) The apparatus is designed for multiple purposes, capable of receiving or playing back video programming transmitted simultaneously with sound but whose essential utility is derived from other purposes.

(h) Complaints alleging violations of the apparatus closed caption requirements.

Consumers may file written complaints alleging violations of the Commission's rules, 47 CFR 79.101–79.104, requiring apparatus designed to receive, play back, or record video programming to be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captions. A written complaint filed with the Commission must be transmitted to the Consumer and Governmental Affairs Bureau through the Commission's online informal complaint filing system, U.S. Mail, overnight delivery, or facsimile. Such complaints should include certain information about the complainant and the alleged violation. The Commission may forward such complaints to the named manufacturer or provider, as well as to any other entity that Commission staff determines may be involved, and may request additional information from any relevant parties when, in the estimation of Commission staff, such information is needed to investigate the complaint or adjudicate potential violations of Commission rules.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary. Office of Secretary, Office of the Managing Director.*

[FR Doc. 2015–10143 Filed 4–30–15; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### FDIC Systemic Resolution Advisory Committee; Notice of Charter Renewal

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice of renewal of the FDIC Systemic Resolution Advisory Committee.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (''FACA''), 5 U.S.C. App., and after consultation with the General Services Administration, the Chairman of the Federal Deposit Insurance Corporation has determined that renewal of the FDIC Systemic Resolution Advisory Committee (''the Committee'') is in the public interest in connection with the performance of duties imposed upon the FDIC by law. The Committee has been a successful undertaking by the FDIC and has provided valuable feedback to the agency on a broad range of issues regarding the resolution of systemically important financial companies pursuant to Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203 (July 21, 2010), 12 U.S.C. 5301 *et seq.* The Committee will continue to provide advice and recommendations on how the FDIC's systemic resolution authority, and its implementation, may impact regulated

entities and other stakeholders potentially affected by the process. The structure and responsibilities of the Committee are unchanged from when it was originally established in May 2011. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

Dated: April 28, 2015.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Committee Management Officer.*

[FR Doc. 2015–10204 Filed 4–30–15; 8:45 am]

**BILLING CODE 6714–01–P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### FDIC Advisory Committee on Economic Inclusion (ComE-IN); Notice of Meeting

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice of open meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Economic Inclusion, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on initiatives to expand access to banking services by underserved populations.

**DATES:** Friday, May 15, 2015, from 9 a.m. to 3 p.m.

**ADDRESSES:** The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The agenda will be focused on affordable small-dollar loans and youth financial education opportunities. The agenda may be subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

*Type of Meeting:* The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This ComE-IN meeting will be Webcast live via the Internet at: *https://fdic.primetime.mediaplatform.com/#/channel/1384299229422/Advisory+Committee+on+Economic+Inclusion.* Questions or troubleshooting help can be found at the same link. For optimal viewing, a high speed internet connection is recommended. The ComE-IN meeting videos are made available on-demand approximately two weeks after the event.

Dated: April 27, 2015.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary, Federal Deposit Insurance Corporation.*

[FR Doc. 2015–10119 Filed 4–30–15; 8:45 am]

**BILLING CODE 6714–01–P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Notice

**AGENCY:** Federal Election Commission.

**DATE AND TIME:** Wednesday, May 6, 2015 AT 2:00 p.m.

**PLACE:** 999 E Street NW., Washington, DC (Ninth Floor).

**STATUS:** This hearing will be open to the public.

**ITEM TO BE DISCUSSED:** Audit Hearing: Gary Johnson 2012, Inc.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary, at (202) 694–1040, at least 72 hours prior to the hearing date.

**PERSON TO CONTACT FOR INFORMATION:** Judith Ingram, Press Officer, Telephone: (202) 694–1220.

**Shawn Woodhead Werth,**

*Secretary and Clerk of the Commission.*

[FR Doc. 2015–10339 Filed 4–29–15; 4:15 pm]

**BILLING CODE 6715–01–P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 28, 2015.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *First Interstate BancSystem, Inc.,* Billings, Montana; to merge with Absarokee Bancorporation, Inc., and thereby indirectly acquire United Bank, both in Absarokee, Montana.

Board of Governors of the Federal Reserve System, April 28, 2015.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2015–10178 Filed 4–30–15; 8:45 am]

**BILLING CODE 6210–01–P**

## FEDERAL TRADE COMMISSION

**[File No. 132 3251]**

### Nomi Technologies, Inc.; Analysis of Proposed Consent Order To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment

describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before May 25, 2015.

**ADDRESSES:** Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/nomitechconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Nomi Technologies, Inc.,—Consent Agreement; File No. 132 3251'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/nomitechconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''Nomi Technologies, Inc.,—Consent Agreement; File No. 132 3251'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Amanda Koulousias (202–326–3334) or Jacqueline Connor (202–326–2844), Bureau of Consumer Protection, 600 Pennsylvania Avenue NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for April 23, 2015), on the World Wide Web at: *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before May 25, 2015. Write ''Nomi Technologies, Inc.,—Consent Agreement; File No. 132 3251'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

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

If you file your comment on paper, write ''Nomi Technologies, Inc.,—Consent Agreement; File No. 132 3251'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before May 25, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

## Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, a consent order applicable to Nomi Technologies, Inc. (''Nomi'').

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Nomi uses mobile device tracking technology to provide analytics services to brick and mortar retailers through its ''Listen'' service. Nomi has been collecting information from consumers' mobile devices to provide the Listen service since January 2013. Nomi places sensors in its clients' retail locations that detect the media access control (''MAC'') address broadcast by a mobile device when it searches for WiFi networks. A MAC address is a 12-digit identifier that is unique to a particular device. Alternatively, in some instances Nomi collects MAC addresses through its clients' existing WiFi access points. In addition to the MAC address, Nomi

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

also collects the following information about each mobile device that comes within range of its sensors or its clients' WiFi access points: The mobile device's signal strength; the mobile device's manufacturer (derived from the MAC address); the location of the sensor or WiFi access point observing the mobile device; and the date and time the mobile device is observed.

Nomi cryptographically hashes the MAC addresses it observes prior to storing them on its servers. Hashing obfuscates the MAC address, but the result is still a persistent unique identifier for that mobile device. Each time a MAC address is run through the same hash function, the resulting identifier will be the same. For example, if MAC address 1A:2B:3C:4D:5E:6F is run through Nomi's hash function on ten different occasions, the resulting identifier will be the same each time. As a result, while Nomi does not store the MAC address, it does store a persistent unique identifier for each mobile device. Nomi collected information about approximately nine million unique mobile devices between January 2013 and September 2013.

Nomi uses the information it collects to provide analytics reports to its clients about aggregate customer traffic patterns such as: The percentage of consumers merely passing by the store versus entering the store; the average duration of consumers' visits; types of mobile devices used by consumers visiting a location; the percentage of repeat customers within a given time period; and the number of customers that have also visited another location within the client's chain. Through October 22, 2013, Nomi's Listen service had approximately 45 clients. Some of these clients deployed the service in multiple locations within their chains.

Nomi has not published, or otherwise made available to consumers, a list of the retailers that use or used the Listen service. Nomi does not require its clients to post disclosures or otherwise notify consumers that they use the Listen service. Through October 22, 2013, most, if not all, of Nomi's clients did not post any disclosure, or otherwise notify consumers, regarding their use of the Listen service.

From at least November 2012, until October 22, 2013, Nomi disseminated or caused to be disseminated privacy policies on its Web site, *nomi.com* or *getnomi.com,* which included the following statement:

> Nomi pledges to. . . . Always allow consumers to opt out of Nomi's service on its Web site as well as at any retailer using Nomi's technology.

Nomi provided, and continues to provide, an opt out on its Web site for consumers who do not want Nomi to store observations of their mobile device. In order to opt out of the Listen service on Nomi's Web site, consumers were required to provide Nomi with all of their mobile devices' MAC addresses, without knowing whether they would ever shop at a retail location using the Listen service. Once a consumer has entered the MAC address of their device into Nomi's Web site opt out, Nomi adds it to a blacklist of MAC addresses for which information will not be stored. Consumers who did not opt out on Nomi's Web site and instead wanted to make the opt out decision at retail locations were unable to do so, despite the explicit promise in Nomi's privacy policies. Consumers were not provided any means to opt out at retail locations and were unaware that the service was even being used.

The Commission's complaint alleges that Nomi's privacy policy represented that: (1) Consumers could opt out of Nomi's Listen service at retail locations using this service, and (2) that consumers would be given notice when a retail location was utilizing Nomi's Listen service. The complaint alleges that Nomi violated Section 5 of the Federal Trade Commission Act by misleading consumers because, contrary to its representations, Nomi did not provide an opt-out mechanism at its clients' retail locations and neither Nomi nor its clients disclosed to consumers that Nomi's Listen service was being used at a retail location.

The proposed order contains provisions designed to prevent Nomi from engaging in the future in practices similar to those alleged in the complaint. Part I of the proposed order prohibits Nomi from misrepresenting: (A) The options through which, or the extent to which, consumers can exercise control over the collection, use, disclosure, or sharing of information collected from or about them or their computers or devices, or (B) the extent to which consumers will be provided notice about how data from or about a particular consumer, computer, or device is collected, used, disclosed, or shared.

Parts II through VI of the proposed order are reporting and compliance provisions. Part II requires Nomi to retain documents relating to its compliance with the order. The order requires that all of the documents be retained for a five-year period. Part III requires dissemination of the order now and in the future to all current and future subsidiaries, principals, officers, directors, and managers, and to persons with responsibilities relating to the subject matter of the order. Part IV ensures notification to the FTC of changes in corporate status. Part V mandates that Nomi submit a compliance report to the FTC within 90 days, and periodically thereafter as requested. Part VI is a provision ''sunsetting'' the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed complaint or order or to modify the order's terms in any way.

By direction of the Commission, Commissioners Ohlhausen and Wright dissenting.

**Donald S. Clark,**

*Secretary.*

**Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeny**

We write to express our support for the complaint and proposed consent order in this case.

Nomi Technologies, Inc. is a provider of technology services that allow retailers to track consumers' movements around their stores by detecting the media access control (''MAC'') addresses broadcast by the WiFi interface on consumers' mobile devices.[1] Services like Nomi's benefit businesses and consumers. For example, they enable retailers to improve store layouts and reduce customer wait times.

At the same time, Nomi's service, and others like it, raise privacy concerns because they rely on the collection and use of consumers' precise location data. Indeed, Nomi sought to assure consumers that its practices were privacy-protecting, declaring in its privacy policy that ''privacy is our first priority.'' A core element of Nomi's assurance was its promise that consumers could opt out of Nomi's service through its Web site ''as well as at any retailer using Nomi's technology.'' Thus, Nomi made a specific and express promise to consumers about how, when, and where they could opt out of the location tracking services that the company provided to its clients.

[1] Although Nomi took steps to obscure the MAC addresses it collected by cryptographically hashing them, hashing generates a unique number that can be used to identify a device throughout its lifetime and is a process that can easily be ''reversed'' to reveal the original MAC address. *See, e.g.,* Jonathan Mayer, *Questionable Crypto in Retail Analytics,* March 19, 2014, *http://webpolicy.org/2014/03/19/questionable-crypto-in-retail-analytics/ (describing successful efforts in ''reversing the hash'' to identify the original MAC address).*

As the Commission alleges in its complaint, however, this express promise was false. At no time during the nearly year-long period that Nomi made this promise to consumers did Nomi provide an in-store opt out at the retailers using its service. Moreover, the express promise of an in-store opt out necessarily makes a second, implied promise: That retailers using Nomi's service would notify consumers that the service was in use. This promise was also false. Nomi did not require its clients to provide such a notice. To our knowledge, no retailer provided such a notice on its own.

The proposed order includes carefully-tailored relief designed to prevent similar violations in the future. Specifically, it prohibits Nomi from making future misrepresentations about the notice and choices that will be provided to consumers about the collection and use of their information.

Nevertheless, Commissioner Wright argues in his dissent that Nomi's express promise to provide an in-store opt-out was not material because a Web site opt-out was available, and that, in any event, the Commission should not have brought this action because it will deter industry from adopting business practices that benefit consumers. In a separate statement, Commissioner Ohlhausen dissents on grounds of prosecutorial discretion. This statement addresses both dissents' arguments.

## I. Nomi's Express Opt-Out Promise Was False and Material, and Therefore Deceptive

According to the Commission's Deception Policy Statement, a deceptive representation, omission, or practice is one that is material and likely to mislead a consumer acting reasonably under the circumstances. ''The basic question [with respect to materiality] is whether the act or practice is likely to affect the consumer's conduct or decision with respect to the product or service.'' [2] Furthermore, the Commission presumes that an express claim is material,[3] as is ''information pertaining to the central characteristics of the product or service.'' [4]

Importantly, Section 5 case law makes clear that ''[m]ateriality is not a test of the effectiveness of the communication in reaching large numbers of consumers. It is a test of the likely effect of the claim on the conduct of a consumer who has been reached and deceived.'' [5]

Consumers who read the Nomi privacy statement would likely have been privacy-sensitive, and claims about how and when they could opt out would likely have especially mattered to them. Some of those consumers could reasonably have decided not to share their MAC address with an unfamiliar company in order to opt out of tracking, as the Web site-based opt-out required. Instead, those consumers may reasonably have decided to wait to see if stores they patronized actually used Nomi's services and opt out then. Or they may have decided that they would simply not patronize stores that use Nomi's services, so that they could effectively ''vote with their feet'' rather than exercising the opt-out choice. Or consumers may simply have found it inconvenient to opt out at the moment they were viewing Nomi's privacy policy, and decided to opt out later.

These choices were rendered illusory because of Nomi's alleged failure to ensure that its client retailers provide any signs or opt-outs at stores. Further, consumers visiting stores that used Nomi's services would have reasonably concluded, in the absence of signage and the promised opt-outs, that these stores did *not* use Nomi's services. Nomi's express representations regarding how consumers may opt out of its location tracking services go to the very heart of consumers' ability to make decisions about whether to participate in these services. Thus, we have ample reason to believe that Nomi's opt-out representations were material.

In his dissent, Commissioner Wright points to certain evidence that, in his view, rebuts the notion that a consumer who viewed Nomi's privacy policy would ''bypass the easier and immediate route (the online opt out) in favor of waiting'' to opt out at a retail location.[6] According to Commissioner Wright, because consumers who viewed Nomi's privacy policy opted out at a higher rate (3.8%) than what is reported for a certain method of opting out of online behavioral advertising (less than 1%),[7] this shows that consumers who wanted to opt out of tracking were able to do so—and therefore, the representation that consumers could opt out at an individual retailer was not material. We do not believe the 3.8% opt-out rate provides reliable evidence to rebut the presumption of materiality.

The benchmark against which Commissioner Wright measures the Nomi opt-out rate—the purported opt out rate for online behavioral advertising—is neither directly comparable to, nor provides meaningful information about, consumers' likely motivations in deciding whether to opt-out of Nomi's Listen service. The difference in opt-out rates could simply mean that the practice of location tracking is much more material to consumers than behavioral advertising, and for that reason a much higher number of consumers exercised the Web site opt out. Indeed, recent studies have shown that consumers are concerned about offline retail tracking and tracking that occurs over time,[8] as took place here. These relative opt-out rates could just as easily imply that many more than 3.8% of consumers were interested in opting out of Nomi's retail tracking, and that the consumers who did not opt out on the Web site were relying on their ability to opt out in stores, as promised by Nomi.

In short, the 3.8% opt-out rate for Nomi's Web site opt-out, along with the comparison to opt-out rates in other contexts, is simply insufficient evidence to evaluate what choices the other 96.2% of visitors to the Web site intended to make, given the promises Nomi made to them about their options. Commissioner Wright is simply speculating when he extrapolates from the available data his conclusion that in-store opt-out rates would have been so low as to render the in-store option immaterial. Such inconclusive evidence fails to rebut any presumption of materiality that we might apply to Nomi's statements.

## II. The Proposed Order Contains Appropriate and Meaningful Relief

The Commission's acceptance of the consent agreement is appropriate in light of both Nomi's alleged deception and the relief in the proposed order. The proposed order addresses the underlying deception in an appropriately tailored way. It prohibits Nomi from misrepresenting the options that consumers have to exercise control over information that Nomi collects, uses, discloses, or shares about them or their devices.[9] It also prohibits Nomi from misrepresenting the extent to

[2] Deception Policy Statement § I.

[3] Deception Policy Statement § IV.

[4] *Id.*

[5] In the Matter of Novartis, 1999 FTC LEXIS 63 *38 (May 27, 1999).

[6] Statement of Commissioner Wright at 4.

[7] *Id.* at 3 & n.15.

[8] *See* New Study: Consumers Overwhelmingly Reject In-store Tracking by Retailers, OpinionLab, March 27, 2014 *http://www.opinionlab.com/press_release/new-study-consumers-overwhelmingly-reject-in-store-tracking-by-retailers/* (44% of survey respondents indicated that they would be less likely to shop at a store that uses in-store mobile device tracking); *Spring Privacy Series: Mobile Device Tracking Seminar, available at http://www.ftc.gov/system/files/documents/public_events/182251/140219mobiledevicetranscript.pdf; Remarks of Ilana Westerman, Create with Context,* at 47–48; 50 (stating that a study of 4600 Americans showed that consumers are reluctant to give up their location histories).

[9] Order § I.

which consumers will be notified about such choices.[10] Nomi may be subject to civil penalties if it violates either of these prohibitions. While the consent order does not require that Nomi provide in-store notice when a store uses its services or offer an in-store opt out, that was not the Commission's goal in bringing this case. This case is simply about ensuring that when companies promise consumers the ability to make choices, they follow through on those promises. The relief in the order is therefore directly tied to the deceptive practices alleged in the complaint.[11] The order will also serve to deter other companies from making similar false promises and encourage them to periodically review the statements they make to consumers to ensure that they are accurate and up-to-date.

In their dissents, however, Commissioners Wright and Ohlhausen argue that the Commission should have declined to take action in this case. Commissioner Ohlhausen views this action as ''encourag[ing] companies to do only the bare minimum on privacy, ultimately leaving consumers worse off.'' [12] Similarly, Commissioner Wright argues that the action against Nomi ''sends a dangerous message to firms weighing the costs and benefits of voluntarily providing information and choice to consumers.'' [13]

The Commission encourages companies to provide privacy choices to consumers, but it also must take action in appropriate cases to stop companies from providing *false* choices. Our action today does just that. Indeed, this case is very similar to prior Commission cases involving allegedly deceptive opt outs.[14] We do not believe that any of these actions—including the one announced today—have deterred or will deter companies from providing truthful choices. To the contrary, companies are voluntarily adopting enforceable privacy commitments in the retail location tracking space [15] and in other areas.[16]

* * * * *

The application of Section 5 deception authority to express statements likely to affect a consumer's choice of or conduct regarding a good or service is well established. For close to a year, Nomi claimed to offer two opt-out methods but in fact it provided only one. We believe this failure was material and that Nomi had a legal obligation to fulfill the promises it made to consumers.

**Dissenting Statement of Commissioner Maureen K. Ohlhausen**

Nomi Technologies Inc., a startup company, offered its retail merchant clients the ability to analyze aggregate data about consumer traffic in the merchants' stores. Nomi provided this service by observing smartphone MAC addresses—a series of hexadecimal numbers that every WiFi-enabled device publicly broadcasts to any listening receiver. Nomi did not store this publicly broadcast information, but instead hashed the addresses and stored the hash. Nomi provided this service as a third party contractor; it had no direct relationship with consumers. At the time covered by the complaint, the majority of Nomi's customers were trialing this startup service in a few stores, at most.

It is important to note that, as a third party contractor collecting no personally identifiable information, Nomi had no obligation to offer consumers an opt out. Yet from the inception of the service, Nomi offered all consumers the opportunity to opt out globally.

For a time, Nomi's privacy policy stated that Nomi ''pledges to . . . Always allow consumers to opt out of Nomi's service on its Web site *as well as at any retailer using Nomi's technology*.'' [1] As already noted, Nomi did offer a global opt out on its Web site. However, it appears that none of Nomi's retail clients offered consumers the opportunity or ability to opt out. Thus, Nomi's privacy policy was partly inaccurate. As Commissioner Wright points out, the evidence we have suggests that the privacy policy's partially inaccurate statement harmed no consumers.[2]

I believe the FTC should not have brought a case against Nomi based on these facts and instead should have exercised its prosecutorial discretion, for two reasons. First, the Commission should use its limited resources to pursue cases that involve consumer harm. Second, and more importantly, we should not apply a *de facto* strict liability approach to a young company that attempted to go above and beyond its legal obligation to protect consumers but, in so doing, erred without benefiting itself. I fear that the majority's decision in this case encourages companies to do only the bare minimum on privacy, ultimately leaving consumers worse off.

For these reasons, I dissent.

**Dissenting Statement of Commissioner Joshua D. Wright**

Today, the Commission finds itself in the unfortunate position of trying to fix a problem that no longer exists by stretching a legal theory to fit the unwieldy facts before it. I dissent from the Commission's decision to accept for public comment a consent order with Nomi Technologies, Inc. (Nomi) not only because it is inconsistent with a fair reading of the Commission's Policy Statement on Deception, but also because even if the facts were to support a technical legal violation—which they do not—prosecutorial discretion would favor restraint.

Nomi does *not* track individual consumers—that is, Nomi's technology records whether individuals are unique or repeat visitors, but it does not identify them. Nomi provides analytics services based upon data collected from mobile device tracking technology to brick-and-mortar retailers through its

[10] *Id.*

[11] After arguing primarily that Nomi did not violate Section 5, Commissioner Wright argues in the alternative that the proposed order is too narrow. *See* Statement of Commissioner Wright at 4 (stating that ''the proposed consent order does nothing to alleviate such harm [from retail location tracking]'' because it does not require Nomi to offer, and provide notice of, an in-store opt out). This argument is based on a misunderstanding of the injury at issue in this case. Here, the injury to consumers was Nomi's allegedly false and material statement of the opt-out choices available to consumers. The proposed order prohibits Nomi from making such representations and thereby addresses the underlying consumer injury.

[12] Statement of Commissioner Ohlhausen.

[13] Statement of Commissioner Wright at 4.

[14] *See U.S.* v. *Google Inc.,* No. CV 12–04177, (N.D. Cal. Nov. 16, 2012) (stipulated injunction) ($22.5 million settlement over Google's allegedly deceptive opt out, which did not work on the Safari browser); *Chitika, Inc.,* No. C–4324, (F.T.C. June 7, 2011) (consent order) *available at http://www.ftc.gov/enforcement/cases-proceedings/1023087/chitika-inc-matter (alleging that advertising network deceived consumers by not telling them that their opt out of behavioral advertising cookies would last only 10 days); U.S. Search, Inc.,* No. C–4317 (Mar. 14, 2011) (consent order) *available at http://www.ftc.gov/enforcement/cases-proceedings/us-search-inc* (alleging that a data broker deceived consumers by failing to disclose limitations of its opt out).

[15] The Future of Privacy Forum has developed an entire self-regulatory code that requires industry members to provide such choices. *See also* Jan Lauren Boyles et al., Pew Internet Project, Privacy and Data Management on Mobile Devices 2 (2012), *available at http://www.pewinternet.org/files/old-media/Files/Reports/2012/PIP_MobilePrivacyManagement.pdf* (reporting that 19% of consumers ''turned off the location tracking feature on their cell phone because they were concerned that other individuals or companies could access that information) *and* Westerman, *supra* note 8, at 50–52 (describing sensitivity of location history, based on study of 4600 U.S. consumers).

[16] *See, e.g.,* Future of Privacy Forum, K–12 Student Privacy Pledge Announced (Oct. 7, 2014), *available at http://www.futureofprivacy.org/2014/10/07/k-12-student-privacy-pledge-announced/.*

[1] Complaint, Exhibit A (Nomi's privacy policy from approximately Nov. 2012 until Jan. 2013) (emphasis added).

[2] Dissenting Statement of Commissioner Joshua Wright at 2.

''Listen'' service.[1] Nomi uses sensors placed in its clients' retail locations or its clients' existing WiFi access points to detect the media access control (MAC) address broadcast by a consumer's mobile device when it searches for WiFi networks. Nomi passes MAC addresses through a cryptographic hash function before collection and creates a persistent unique identifier for the mobile device.[2] Nomi does not ''unhash'' this identifier to retrieve the MAC addresses and Nomi does not store the MAC addresses of the mobile devices. In addition to creating this unique persistent identifier, Nomi collects the device manufacturer information, the device's signal strength, and the date, time and locating sensor of the mobile device. This information is then used to provide analytics to Nomi's clients. For example, even without knowing the identity of those visiting their stores, the data provided by Nomi's Listen service can generate potentially valuable insights about aggregate in-store consumer traffic patterns, such as the average duration of customers' visits, the percentage of repeat customers, or the percentage of consumers that pass by a store rather than entering it. These insights, in turn, allow retailers to measure how different retail promotions, product offerings, displays, and services impact consumers. In short, these insights help retailers optimize consumers' shopping experiences,[3] inform staffing coverage for their stores, and improve store layouts.

The Commission's complaint focuses upon a single statement in Nomi's privacy policy. Specifically, Nomi's privacy policy states that ''Nomi pledges to . . . Always allow consumers to opt out of Nomi's service on its Web site as well as at any retailer using Nomi's technology.'' [4] Count I of the complaint alleges Nomi represented in its privacy policy that consumers could opt out of its Listen service at retail locations using the service, but did not in fact provide a retail level opt out. Count II relies upon this same representation to allege a second deceptive practice—that the failure to provide the opt out in the first instance also implies a failure to provide notice to consumers that a specific retailer would be using the Listen service.[5]

The Commission's decision to issue a complaint and accept a consent order for public comment in this matter is problematic for both legal and policy reasons. Section 5(b) of the FTC Act requires us, before issuing any complaint, to establish ''reason to believe that [a violation has occurred]'' and that an enforcement action would ''be to the interest of the public.'' [6] While the Act does not set forth a separate standard for accepting a consent decree, I believe that threshold should be at least as high as for bringing the initial complaint. The Commission has not met the relatively low ''reason to believe'' bar because its complaint does not meet the basic requirements of the Commission's 1983 Deception Policy Statement. Further, the complaint and proposed settlement risk significant harm to consumers by deterring industry participants from adopting business practices that benefit consumers.

The fundamental failure of the Commission's complaint is that the evidence simply does not support the allegation that Nomi's representation about an opportunity to opt out of the Listen service at the retail level—in light of the immediate and easily accessible opt out available on the Web page itself—was material to consumers. This failure alone is fatal. A representation simply cannot be deceptive under the long-standing FTC Policy Statement on Deception in the absence of materiality.[7] The Policy Statement on Deception highlights the centrality of the materiality inquiry, observing that the ''basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service.'' [8] The materiality inquiry is critical because the Commission's construct of ''deception'' uses materiality as an evidentiary proxy for consumer injury: ''[i]njury exists if consumers would have chosen differently but for the deception. If different choices are likely, the claim is material, and injury is likely as well.'' [9] This is a critical point. Deception causes consumer harm because it influences consumer behavior—that is, the deceptive statement is one that is not merely misleading in the abstract but one that causes cause consumers to make choices to their detriment that they would not have otherwise made. This essential link between materiality and consumer injury ensures the Commission's deception authority is employed to deter only conduct that is likely to harm consumers and does not chill business conduct that makes consumers better off. This link also unifies the Commission's two foundational consumer protection authorities—deception and unfairness—by tethering them to consumer injury.

The Commission does not explain how it finds the materiality requirement satisfied; presumably it does so upon the assumption that ''express statements'' are presumptively material.[10] However, that presumption was never intended to substitute for common sense, evidence, or analysis. Indeed, the Policy Statement on Deception acknowledges the ''Commission will always consider relevant and competent evidence offered to rebut presumptions of materiality.'' [11] Here, the Commission failed to discharge its commitment to duly consider relevant and competent evidence that squarely rebuts the presumption that Nomi's failure to implement an *additional,* retail-level opt out was material to consumers. In other words, the Commission neglects to take into account evidence demonstrating consumers would not ''have chosen differently'' but for the allegedly deceptive representation.

Nomi represented that consumers could opt out on its Web site as well as in the store where the Listen service was being utilized. Nomi did offer a fully functional and operational global opt out from the Listen service on its Web site.[12] Thus, the only remaining

[1] In the Matter of Nomi Technologies, Inc., FTC File No. 132–3251, Compl. ¶ 3 (Apr. 23, 2015).

[2] For more information on cryptographic hashing, see Rob Sobers, *The Definitive Guide to Cryptographic Hash Functions (Part I),* Varonis (Aug. 2, 2012), *http://blog.varonis.com/the-definitive-guide-to-cryptographic-hash-functions-part-1/.*

[3] *See, e.g.,* Alyson Shontell, *It Took Only 13 Days for Former Salesforce Execs to Raise $3 Million for Their Startup, Nomi,* Business Insider (Feb. 11, 2013), *http://www.businessinsider.com/former-salesforce-and-buddy-media-executives-raise-3-million-nomi-2013-2* (''The moment you open Amazon.com, your entire retail experience is personalized, down to the promotions you see and the products you are pushed. That's because e-commerce is a data-driven industry, and Web sites know a lot about customers who stumble on to their Web sites. Physical stores however, where 90% of all retail purchases still occur, know nothing about the customers who walk in their doors.'').

[4] Compl. ¶ 12.

[5] Compl. ¶ 16–17.

[6] 15 U.S.C. 45(b).

[7] Fed. Trade Comm'n, Policy Statement on Deception (1983), *appended to* Cliffdale Assocs., Inc., 103 F.T.C. 110, 175, 182 (1984) [hereinafter FTC Policy Statement on Deception], *available at https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception.*

[8] FTC Policy Statement on Deception, 103 F.T.C. at 175.

[9] *Id.* at 183.

[10] *See* POM Wonderful LLC, 2013 FTC LEXIS 6, *121 (2013); Novartis Corp., 127 F.T.C. 580, 686 (1999); American Home Prods., 98 F.T.C. 136, 368 (1981).

[11] FTC Policy Statement on Deception, 103 F.T.C. at 182 n.47.

[12] As such, the facts of this case are distinguishable from the cases cited for support by the majority in its statement. In the Matter of Nomi Technologies, Inc., FTC File No. 132–3251, Statement of Chairwoman Ramirez, Commissioner

potential issue is whether Nomi's failure to offer the represented in-store opt out renders the statement in its privacy policy deceptive. The evidence strongly implies that specific representation was not material and therefore not deceptive. Nomi's ''tracking'' of users was widely publicized in a story that appeared on the front page of *The New York Times,*[13] a publication with a daily reach of nearly 1.9 million readers.[14] Most likely due to this publicity, Nomi's Web site received 3,840 unique visitors during the relevant timeframe and received 146 opt outs—an opt-out rate of 3.8% of site visitors. This opt-out rate is significantly higher than the opt-out rate for other online activities.[15] This high rate, relative to Web site visitors, likely reflects the ease of a mechanism that was immediately and quickly available to consumers at the time they may have been reading the privacy policy.

The Commission's reliance upon a presumption of materiality as to the additional representation of the availability of an in-store opt out is dubious in light of evidence of the opt-out rate for the Web page mechanism. Actual evidence of consumer behavior indicates that consumers that were interested in opting out of the Listen service took their first opportunity to do so. To presume the materiality of a representation in a privacy policy concerning the availability of an *additional,* in-store opt-out mechanism requires one to accept the proposition that the privacy-sensitive consumer would be more likely to bypass the easier and immediate route (the online opt out) in favor of waiting until she had the opportunity to opt out in a physical location. Here, we can easily dispense with shortcut presumptions meant to aid the analysis of consumer harm rather than substitute for it. The data allow us to know with an acceptable level of precision how many consumers—3.8% of them—reached the privacy policy, read it, and made the decision to opt out when presented with that immediate choice. The Commission's complaint instead adopts an approach that places legal form over substance, is inconsistent with the available data, and defies common sense.

The Commission's approach here is problematic for another reason. To the extent there is consumer injury when consumers are offered an opt out from tracking that cannot be effectuated, or that more generally, consumers are uncomfortable with such tracking and it should be disclosed to them, the proposed consent order does nothing to alleviate such harm and will, instead, likely exacerbate it. Nomi has removed its representation about a retail level opt-out mechanism from its privacy policy. The proposed consent order does not require Nomi to offer such a mechanism, nor does it require Nomi to disclose the tracking in retail locations.[16] It is unlikely that Nomi could agree to such a condition any case—Nomi contracts with retailers and has no control over the retailers' premises. The order does not—and cannot—compel retailers to disclose the tracking technology.

Even assuming *arguendo* Nomi's privacy policy statement is deceptive under the Deception Policy Statement, the FTC would better serve consumers by declining to take action against Nomi. The analytical failings of the Commission's approach are not harmless error. Rather, aggressive prosecution of this sort will inevitably deter industry participants like Nomi from engaging in voluntary practices that promote consumer choice and transparency—the very principles that lie at the heart of the Commission's consumer protection mission.[17] Nomi was under no legal obligation to post a privacy policy, describe its practices to consumers, or to offer an opt-out mechanism. To penalize a company for such a minor shortcoming—particularly when there is no evidence the misrepresentation harmed consumers—sends a dangerous message to firms weighing the costs and benefits of voluntarily providing information and choice to consumers.

Finally, market forces already appear to be responding to consumer preferences related to tracking technology. For example, in response to potential consumer discomfort some retailers have discontinued or changed the methods by which they track visitors to their physical stores.[18] Technological innovation has also responded to incentives to provide a better consumer experience, including a Bluetooth technology that provides not only an opt-in choice for consumers,[19] but also gives retailers the opportunity to provide their consumers with a more robust shopping experience.[20] Notably, Nomi itself has responded to these market changes and no longer offers the MAC address tracking technology to any retailer other than its legacy customers.

Accordingly, I dissent from the issuance of this complaint and the acceptance of a consent decree for public comment.

[FR Doc. 2015–10154 Filed 4–30–15; 8:45 am]

BILLING CODE 6750–01–P

Brill, and Commissioner McSweeny 5 n.14 (Apr. 23, 2015).

[13] Stephanie Clifford & Quentin Hardy, *Attention, Shoppers: Store is Tracking Your Cell,* New York Times (July 14, 2013), *http://www.nytimes.com/2013/07/15/business/attention-shopper-stores-are-tracking-your-cell.html?pagewanted=all&_r=0.*

[14] The Associated Press, *Top 10 Newspapers by Circulation: Wall Street Journal Leads Weekday Circulation,* Huffington Post (Apr. 30, 2013), *http://www.huffingtonpost.com/2013/05/01/newspaper-circulation-top-10_n_3188612.html.*

[15] In perhaps the most comparable circumstance—Do Not Track mechanisms—the opt-out rate is extremely low. *See, e.g.,* Jack Marshall, *The Do Not Track Era,* Digiday (Feb. 27, 2012), *http://digiday.com/platforms/advertising-in-the-do-not-track-era/* (''[a]ccording to data from Evidon, which facilitates the serving of those icons, someone clicks and goes through the opt-out process once for every 10,000 ad impressions served''); Matthew Creamer, *Despite Digital Privacy Uproar, Consumers are Not Opting Out,* Advertising Age (May 31, 2011), *http://adage.com/article/digital/digital-privacy-uproar-consumers-opting/227828/* (''Evidon, which has the longest set of data, is seeing click-through of 0.005% with only 2% opting out from 30 billion impressions''). *See also* Richard Beaumont, *Cookie Opt-Out Stats Revealed,* The Cookie Collective (Feb. 19, 2014), *http://www.cookielaw.org/blog/2014/2/19/cookie-opt-out-statistics-revealed/.*

[16] In the Matter of Nomi Technologies, Inc., FTC File No. 132–3251, Proposed Consent Order Part I (Apr. 23, 2015).

[17] In addition, Nomi arguably offered a product that was more privacy-protective than other, more intrusive methods that retailers currently employ, such as video cameras. *See* Clifford & Hardy, *supra* note 14 (''Cameras have become so sophisticated, with sharper lenses and data-processing, that companies can analyze what shoppers are looking at, and even what their mood is.'').

[18] *See, e.g.,* Amy Hollyfield, *Philz to Stop Tracking Customers via Smartphones,* ABC 7 News (May 29, 2014), *http://abc7news.com/business/philz-to-stop-tracking-customers-via-smartphones/83943/;* Peter Cohan, *How Nordstrom Uses WiFi to Spy On Shoppers, Forbes* (May 9, 2013), *http://www.forbes.com/sites/petercohan/2013/05/09/how-nordstrom-and-home-depot-use-wifi-to-spy-on-shoppers/.*

[19] *See, e.g.,* Siraj Datoo, *High Street Shops are Studying Shopper Behaviour by Tracking Their Smartphones or Movement,* The Guardian (Oct. 3, 2013), *http://www.theguardian.com/news/datablog/2013/oct/03/analytics-amazon-retailers-physical-cookies-high-street* (''If customers create accounts on the wireless network—something millions have done—they first have to accept terms and conditions that opts them in to having their movements monitored when inside the stores''); Jess Bolluyt, *What's So Bad About In-Store Tracking?,* The Cheat Sheet (Nov. 27, 2014), *http://www.cheatsheet.com/technology/whats-so-bad-about-in-store-tracking.html/?a=viewall* (''customers have to turn on Bluetooth, accept location services, and opt in to receive notifications'').

[20] *See, e.g.,* Greg Petro, *How Proximity Marketing Is Driving Retail Sales,* Forbes (Oct. 8, 2014), *http://www.forbes.com/sites/gregpetro/2014/10/08/how-proximity-marketing-is-driving-retail-sales/* (''[This will] allow Macy's to send personalized department-level deals, discounts, recommendations and rewards to customers who opt-in to receive the offers''); Datoo, *supra* note 20 (after opting in, ''[u]sers can then add their loyalty card numbers to receive personalised recommendations.'').

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Docket Number CDC–2015–0020; NIOSH 156–A]**

### Request for the Technical Review of 14 Draft Immediately Dangerous to Life or Health (IDLH) Value Profiles

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Request for information and comment.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is conducting a public review of the draft immediately dangerous to life or health (IDLH) values and support technical documents, entitled IDLH Values Profiles, for 14 chemicals. NIOSH is requesting technical reviews of the draft IDLH Value Profiles.

**DATES:** Electronic or written comments on the 14 documents contained within Group A must be received on or before June 30, 2015.

**ADDRESSES:** You may submit comments, identified by CDC–2015–0020 and docket number NIOSH 156–A, by either of the two following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, OH 45226.

*Instructions:* All information received in response to this notice must include the agency name and docket number [CDC–2015–0020; NIOSH 156–A]. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background documents or comments received, go to *www.regulations.gov.* All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226.

**FOR FURTHER INFORMATION CONTACT:** G. Scott Dotson, NIOSH, Robert A. Taft Laboratories, MS C–32, 1090 Tusculum Avenue, Cincinnati, OH 45226. (513) 533–8540 (not a toll free number).

**SUPPLEMENTARY INFORMATION:** The draft documents are based on the process outlined in the NIOSH Current Intelligence Bulletin 66—Derivation of Immediately Dangerous to Life or Health (IDLH) Values *http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf.* To facilitate the review of these documents, NIOSH requests that the following questions be taken into consideration:

1. Does this document clearly outline the health hazards associated with acute (or short-term) exposures to the chemical? If not, what specific information is missing from the document?
2. Are the rationale and logic behind the derivation of an IDLH value for a specific chemical clearly explained? If not, what specific information is needed to clarify the basis of the IDLH value?
3. Are the conclusions supported by the data?
4. Are the tables clear and appropriate?
5. Is the document organized appropriately? If not, what improvements are needed?
6. Are you aware of any scientific data reported in governmental publications, databases, peer-reviewed journals, or other sources that should be included within this document?

NIOSH seeks comments on 14 draft IDLH values and IDLH Value Profiles. The draft IDLH Value Profiles were developed to provide the scientific rationale behind derivation of IDLH values for the following chemicals:

| Document No. | Chemical(s) | |
|---|---|---|
| A–01 | Acrylonitrile | (CAS# 107–13–1) |
| A–02 | Benzonitrile | (CAS# 100–47–0) |
| A–03 | Methyl isocyanate | (CAS# 624–83–9) |
| A–04 | HCFC–141B | (CAS# 1717–00–6) |
| A–05 | Chloroacetyl chloride | (CAS# 79–04–9) |
| A–06 | Chlorine pentafluoride | (CAS# 13637–63–3) |
| | Bromine pentafluoride | (CAS# 7789–30–2) |
| A–07 | Iron pentacarbonyl | (CAS# 13463–40–6) |
| A–08 | 1,3-Butadiene | (CAS# 106–99–0) |
| A–09 | Diketene | (CAS# 674–82–8) |
| A–10 | Furan | (CAS# 110–00–9) |
| A–11 | Hexafluoroacetone | (CAS# 684–16–2) |
| A–12 | n-Butyl acrylate | (CAS# 141–32–2) |
| A–13 | Peracetic acid | (CAS# 79–21–0) |
| A–14 | Butane | (CAS# 106–97–8). |

Each IDLH Value Profile provides a detailed summary of the health hazards of acute exposures to high airborne concentrations and the rationale for the proposed IDLH value with the chemical(s) of interest.

In 2013, NIOSH published Current Intelligence Bulletin (CIB) 66—Derivation of Immediately Dangerous to Life or Health (IDLH) Values [NIOSH 2014–100; *http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf*]. The draft documents available for public review use the methodology in this document. Since the establishment of the IDLH values in the 1970s, NIOSH has continued to review available scientific data to improve the protocol used to derive acute exposure guidelines, in addition to the chemical-specific IDLH values. The information presented in this CIB represents the most recent update of the scientific rationale and the methodology (hereby referred to as the IDLH methodology) used to derive IDLH values. The primary objectives of this document are to:

1. Provide a brief history of the development of IDLH values
2. Update the scientific basis and risk assessment methodology used to derive IDLH values from quality data
3. Provide transparency behind the rationale and derivation process for IDLH values

4. Demonstrate how scientifically credible IDLH values can be derived from available data resources

The IDLH methodology outlined in this CIB reflects the modern principles and understanding in the fields of risk assessment, toxicology, and occupational health and provides the scientific rationale for the derivation of IDLH values based on contemporary risk assessment practices. According to this protocol, IDLH values are based on health effects considerations determined through a critical assessment of the toxicology and human health effects data. This approach ensures that the IDLH values reflect an airborne concentration of a substance that represents a high-risk situation that may endanger workers' lives or health. Relevant airborne concentrations are typically addressed through the characterization of inhalation exposures; however, airborne chemicals can also contribute to toxicity through other exposure routes, such as the skin and eyes. In this document, airborne concentrations are referred to as acute inhalation limits or guidelines to adhere to commonly used nomenclature.

The emphasis on health effects is consistent with both the traditional use of IDLH values as a component of the respirator selection logic and the growing applications of IDLH values in Risk Management Plan (RMPs) for non-routine work practices governing operations in high-risk environments (*e.g.,* confined spaces) and the development of Emergency Preparedness Plans (EPPs). Incorporated in the IDLH methodology are the standing guidelines and procedures used for the development of community-based acute exposure limits called Acute Exposure Guideline Levels (AEGLs). The inclusion of the AEGL methodology has helped ensure that the health-based IDLH values derived with use of the guidance provided in this document are based on validated scientific rationale.

The IDLH methodology is based on a weight-of-evidence approach that applies scientific judgment for critical evaluation of the quality and consistency of scientific data and in extrapolation from the available data to the IDLH value. The weight-of-evidence approach refers to critical examination of all available data from diverse lines of evidence and the derivation of a scientific interpretation on the basis of the collective body of data, including its relevance, quality, and reported results. This is in contrast to a purely hierarchical or strength-of-evidence approach, which relies on rigid decision criteria for selecting a critical adverse effect, a point of departure (POD), or the point on the dose–response curve from which dose extrapolation is initiated and for applying default uncertainty factors (UFs) to derive the IDLH value. Conceptually, the derivation process for IDLH values is similar to that used in other risk assessment applications, including these steps:

1. Hazard characterization.
2. Identification of critical adverse effects.
3. Identification of a POD.
4. Application of appropriate UFs, based on the study and POD.

Dated: April 24, 2015.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2015–10295 Filed 4–30–15; 8:45 am]

BILLING CODE 4163–19–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–15–15IG]**

### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) 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; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) 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; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC 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**

Public Health Associate Program (PHAP) Alumni Assessment—New—Office for State, Tribal, Local, and Territorial Support (OSTLTS)—(proposed), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Centers for Disease Control and Prevention (CDC) works to protect America from health, safety and security threats, both foreign and in the U.S. CDC strives to fulfill this mission, in part, through a competent and capable public health workforce. One mechanism to developing the public health workforce is through training programs like the Public Health Associate Program (PHAP).

The mission of PHAP is to train and provide experiential learning to early career professionals who contribute to the public health workforce. PHAP targets recent graduates with bachelors or masters degrees who are beginning a career in public health. Each year, a new cohort of up to 200 associates is enrolled in the program. Associates are CDC employees who complete two-year assignments in a host site (*i.e.,* a state, tribal, local, or territorial health department or non-profit organization). Host sites design their associates' assignments to meet their agency's unique needs while also providing on-the-job experience that prepares associates for future careers in public health. Associates also receive CDC-based training in core public health concepts and topics to provide the knowledge, skills, and abilities necessary to succeed in their assignments and provide a foundation for a career in public health. PHAP hosts an initial in-person orientation and annual public health training at CDC and offers long-distance learning opportunities throughout the program. It is the goal of PHAP that following participation in the two-year program, alumni will seek employment within the public health system (*i.e.,* federal,

state, tribal, local, or territorial health agencies, or non-governmental organizations), focusing on public health or health/healthcare.

When PHAP originated in 2007, the program focused on increasing recruitment and enrollment; to date, there has been limited systematic assessment of the program. As a result, one current program priority is focused on documenting program outcomes to inform refinements to program processes and activities, demonstrate program impact, and inform decision making about future program direction. The purpose of this information collection request (ICR) is to gain approval to follow alumni career progression following participation in PHAP. The ICR will enable the program to demonstrate evidence of program outcomes, specifically to document how many alumni are retained as members of the public health workforce, where alumni are employed, what topical and functional public health areas alumni support (*e.g.,* chronic disease, infectious disease, assessment, communications, etc.), to what extent alumni support the capabilities of public health agencies at the federal, state, territorial, local, tribal, and non-governmental organizational levels, and to what extent PHAP has influenced alumni career paths (if at all). Information will be used to answer key program assessment questions, specifically: ''Is PHAP a quality program?'', ''Is PHAP an effective program?'', and ''What is the impact of PHAP?''

CDC will administer the PHAP Alumni Assessment at two different time points (1 year post-graduation, and 3 years post-graduation) to PHAP alumni. Assessment questions will remain consistent at each administration (*i.e.,* 1 year, or 3 years post-PHAP graduation). The language, however, will be updated for each assessment administration to reflect the appropriate time period. It is estimated that there will be no more than 480 respondents (160 respondents annually) over the course of the three year approval period. Assessments will be administered electronically; each alumnus will receive an embedded link in an email invitation that is unique to that alumnus; each alumnus will only have access to his/her link to the assessment Web site. The total estimated burden is 8 minutes per respondent per assessment. The total annualized estimated burden is 21 hours.

There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|---|
| PHAP Alumni | PHAP Alumni Assessment | 160 | 1 | 8/60 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2015–10183 Filed 4–30–15; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Docket Number CDC–2015–0021, NIOSH 153–C]**

### Request for the Technical Review of 19 Draft Skin Notation Assignments and Skin Notation Profiles

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Request for information and comment.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is conducting a public review of the draft skin notations and supporting technical documents entitled, Skin Notations Profiles, for 19 chemicals. NIOSH is requesting technical reviews of the draft Skin Notation Profiles.

**DATES:** Electronic or written comments must be received by June 30, 2015.

**ADDRESSES:** You may submit comments, identified by CDC–2015–0021 and docket number NIOSH 153–C, by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

*Instructions:* All information received in response to this notice must include the agency name and docket number [CDC–2015–0021; NIOSH 153–C]. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background documents or comments received, go to *www.regulations.gov.* All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226–1998.

**FOR FURTHER INFORMATION CONTACT:** Naomi Hudson, NIOSH Robert A. Taft Laboratories, MS–C32, 1190 Tusculum Ave., Cincinnati, OH 45226. (513)533–8388 (not a toll free number).

**SUPPLEMENTARY INFORMATION:** This review follows the publication of 22 Skin Notation Profiles, Docket Number NIOSH 153–A *http://www.cdc.gov/niosh/docket/archive/docket153A.html* and the external review of an additional 25 Skin Notation Profiles, Docket Number NIOSH 153–B *http://www.cdc.gov/niosh/docket/archive/docket153B.html.* To facilitate the review of these documents, NIOSH requests that the following questions be taken into consideration for each Skin Notation Profile:

1. Does this document clearly outline the systemic health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

2. If the SYS or SYS (FATAL) notations are assigned, are the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (*e.g.,* insufficient data, no identified health hazard)?

3. Does this document clearly outline the direct (localized) health hazards

associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

4. If the DIR, DIR (IRR), or DIR (COR) notations are assigned, are the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (*e.g.,* insufficient data, no identified health hazard)?

5. Does this document clearly outline the immune-mediated responses (allergic response) health hazards associated with exposures of the skin to the chemical? If not, what specific information is missing from the document?

6. If the SEN notation is assigned, are the rationale and logic behind the assignment clear? If not assigned, is the logic clear why it was not (*e.g.,* insufficient data, no identified health hazard)?

7. If the ID (SK) or SK were assigned, are the rationale and logic outlined within the document?

8. Are the conclusions supported by the data?

9. Are the tables clear and appropriate?

10. Is the document organized appropriately? If not, what improvements are needed?

11. Are you aware of any scientific data reported in governmental publications, databases, peer-reviewed journals, or other sources that should be included within this document?

In 2009, NIOSH published Current Intelligence Bulletin (CIB) 61—A Strategy for assigning New NIOSH Skin Notations [NIOSH 2009–147; *http://www.cdc.gov/niosh/docs/2009-147/pdfs/2009-147.pdf*]. The CIB presents a strategic framework that is a form of hazard identification that has been designed to do the following:

1. Ensure that the assigned skin notations reflect the contemporary state of scientific knowledge

2. Provide transparency behind the assignment process

3. Communicate the hazards of chemical exposures of the skin

4. Meet the needs of health professionals, employers, and other interested parties in protecting workers from chemical contact with the skin.

This strategy involves the assignment of multiple skin notations for distinguishing systemic (SYS), direct (DIR), and sensitizing (SEN) effects caused by exposure of skin (SK) to chemicals. Chemicals that are highly or extremely toxic and may be potentially lethal or life-threatening following exposures of the skin are designated with the systemic subnotation (FATAL). Potential irritants and corrosive chemicals are indicated by the direct effects subnotations (IRR) and (COR), respectively. Thus with the new strategy, chemicals labeled as SK: SYS are recognized to contribute to systemic toxicity through dermal absorption. Chemicals assigned the notation SK: SYS (FATAL) have been identified as highly or extremely toxic and have the potential to be lethal or life-threatening following acute contact with the skin. Substances identified to cause direct effects (*i.e.,* damage or destruction) to the skin limited to or near the point of contact are labeled SK: DIR, and those resulting in skin irritation and corrosion at the point of contact are labeled as SK: DIR (IRR) and SK: DIR (COR), respectively. The SK: SEN notation is used for substances identified as causing or contributing to allergic contact dermatitis (ACD) or other immune-mediated responses, such as airway hyper reactivity (asthma). Candidate chemicals may be assigned more than one skin notation when they are identified to cause multiple effects resulting from skin exposure. For example, if a chemical is identified as corrosive and also contributes to systemic toxicity, it will be labeled as SK: SYS–DIR (COR). When scientific data for a chemical indicate that skin exposure does not produce systemic, direct, or sensitizing effects, the compound will be assigned the notation (~~SK~~). The ID$^{(SK)}$ notation is assigned to indicate that insufficient data on the health hazards associated with skin exposure to a substance exist at the time of the review to determine whether the chemical has the potential to act as a systemic, direct, or sensitizing agent. The ND notation indicates that a chemical has not been evaluated by the strategy outlined in this CIB and that the health hazards associated with skin exposure are unknown.

Historically, skin notations have been published in the NIOSH Pocket Guide to Chemical Hazards [NIOSH 2005–149, *http://www.cdc.gov/niosh/npg/*]. This practice will continue with the NIOSH skin notation assignments for each evaluated chemical being integrated as they become available. A support document called a Skin Notation Profile has been developed for each evaluated chemical. NIOSH submitted the first group of Skin Notation Profiles for external review in 2010 [75 FR 22148] and published the finalized reports in 2011 *[http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html]*. The Skin Notation Profile for a chemical is intended to provide information supplemental to the skin notation, including a summary of all relevant data used to aid in determining the hazards associated with skin exposures.

NIOSH seeks comments on the draft skin notation assignments and Skin Notation Profiles for 19 chemicals. The draft Skin Notation Profiles were developed to provide the scientific rationale behind the hazard-specific skin notation (SK) assignments for the following chemicals:

| Substance(s) | |
|---|---|
| Trichloroethylene | (CAS #79–01–06) |
| Acrylic acid | (CAS #79–10–7) |
| Tetraethyl lead | (CAS #78–00–2) |
| Tetramethyl lead | (CAS #75–74–1) |
| 2-Hydropropyl acrylate | (CAS #999–61–1) |
| Dimethyl sulfate | (CAS #77–78–1) |
| Arsenic | (CAS #7440–38–2) |
| Pentachlorophenol | (CAS #87–86–5) |
| Dichlorvos | (CAS #62–73–7) |
| Heptachlor | (CAS #76–44–8) |
| Disulfoton | (CAS #298–04–4) |
| Atrazine | (CAS #1912–24–9) |
| Morpholine | (CAS #110–91–8) |
| EPN | (CAS #2104–64–5) |
| Sodium fluoroacetate | (CAS #62–74–8) |
| Chlorinated camphene | (CAS #8001–35–2) |
| Dioxathion | (CAS#78–34–2) |
| Catechol | (CAS #120–80–9) |

| Substance(s) | |
|---|---|
| 1-Bromopropane | (CAS #106–94–5) |

Each Skin Notation Profile provides a detailed summary of the health hazards of skin contact and rationale for the proposed SK assignment with the chemical(s) of interest.

Dated: April 22, 2015.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2015–10289 Filed 4–30–15; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10261, CMS–10185 and CMS–2540–10]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by *June 30, 2015*:

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:**

### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS–10261 Part C Medicare Advantage Reporting Requirements and Supporting Regulations**

**CMS–10185 Medicare Part D Reporting Requirements and Supporting Regulations**

**CMS–2540 Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report Form**

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations; *Use:* There are a number of information users of Part C reporting data, including our central and regional office staff that use this information to monitor health plans and to hold them accountable for their performance, researchers, and other government agencies such as the Government Accounting Office. Health plans can use this information to measure and benchmark their performance. *Form Number:* CMS–10261 (OMB Control Number 0938–1054); *Frequency:* Yearly and semi-annually; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 561; *Total Annual Responses:* 3,508; *Total Annual Hours:* 201,503. (For policy questions regarding this collection contact Terry Lied at 410–786–8973).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* To ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries, the collected information will serve as an integral resource for oversight, monitoring, compliance, and auditing activities. Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting. For CY 2016 reporting, the following sections will be reported

and collected at the Contract-level or Plan-level: (1) Enrollment and disenrollment, (2) retail, home infusion, and long-term care pharmacy access, (3) medication therapy management programs, (4) grievances, (5) coverage determinations and redeterminations, (6) long term care utilization, (7) employer/union sponsored sponsors, and (8) plan oversight of agents. *Form Number:* CMS–10185 (OMB control number 0938–0992); *Frequency:* Yearly and semi-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 694; *Total Annual Responses:* 6,875; *Total Annual Hours:* 10,865. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report Form; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS–2540–10 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. The revisions made to the SNF cost report are in accordance with the statutory requirement for hospice payment reform in § 3132 of the Patient Protection and Affordable Care Act (ACA). *Form Number:* CMS–2540–10 (OMB control number 0938–0463); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 14,398; *Total Annual Responses:* 14,398; *Total Annual Hours:* 2,908,396. (For policy questions regarding this collection contact Amelia Citerone at 410–786–8008).

Dated: April 28, 2015.

**William N. Parham III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015–10208 Filed 4–30–15; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10500 and CMS–R–306]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by *June 1, 2015.*

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey; *Use:* The information collected in the national implementation of Outpatient/Ambulatory Surgery Patient Experience of Care Survey (A/ASPECS) will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries to help them make informed decisions for outpatient surgery facility selection; (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; and (3) provide us with information for monitoring and public reporting purposes. The package has been revised subsequent to the publication of the 60-day **Federal Register** notice (January 16, 2015; 80 FR 2430). Previously, the package was entitled, ''Outpatient/Ambulatory Surgery Patient Experience of Care Survey (O/ASPECS).'' *Form Number:* CMS–10500 (OMB Control Number: 0938–1240); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 2,813,610; *Total Annual Responses:* 2,813,610; *Total Annual Hours:* 365,769. (For policy questions regarding this

collection contact Memuna Ifedirah at 410–786–6849).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations; *Use:* Psychiatric residential treatment facilities are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and seclusion. *Form Number:* CMS–R–306 (OMB Control Number 0938–0833); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 390; *Total Annual Responses:* 1,466,795; *Total Annual Hours:* 431,062. (For policy questions regarding this collection contact Cindy Ruff at 410–786–5916).

Dated: April 28, 2015.

**William N. Parham III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015–10207 Filed 4–30–15; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Findings of Research Misconduct

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

*Venkata J. Reddy, University of Minnesota:* Based upon the evidence and findings of an investigation report by the University of Minnesota (UMN), an investigation conducted by another Federal agency, and additional information obtained by the Office of Research Integrity (ORI) during its oversight review of the UMN investigation, ORI found that Mr. Venkata J. Reddy, former Graduate Student, Department of Chemistry, UMN, engaged in research misconduct in research that was included in grant application R01 GM095559–01A1, submitted to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

ORI found by a preponderance of the evidence that the Respondent intentionally and knowingly engaged in research misconduct by falsifying and/or fabricating data that was provided to his mentor to include in grant application R01 GM095559–01A1 submitted to NIGMS, NIH, to obtain U.S. Public Health Service (PHS) funds. Specifically, ORI found that the Respondent falsified data included in Figures 4, 9, 11, 15, and 25 in R01 GM095559–01A1 for enantiomeric excess (''ee'') to falsely show a high degree of selectivity for one enantiomer over another by a cut-and-paste method and manipulation of the instrument to give the desired result. Respondent also falsified the underlying nuclear magnetic resonance spectroscopy (NMR) data for Compound 22 reported in Figure 15 in R01 GM095559–01A1 by a cut-and-paste method to manipulate the NMR spectra and give the desired result.

Dr. Reddy has been debarred by the Federal agency with joint jurisdiction for a period of five (5) years, ending on August 26, 2018. ORI has implemented the following administrative action to coincide with the government-wide debarment:

(1) Respondent is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

**FOR FURTHER INFORMATION CONTACT:** Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

**Donald Wright,**

*Acting Director, Office of Research Integrity.*

[FR Doc. 2015–10203 Filed 4–30–15; 8:45 am]

**BILLING CODE 4150–31–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries

**AGENCY:** Office of the Secretary, HHS.

**SUMMARY:** Through this final recommendation, the U.S. Public Health Service (PHS) updates and replaces its 1962 Drinking Water Standards related to community water fluoridation—the controlled addition of a fluoride compound to a community water supply to achieve a concentration optimal for dental caries prevention. For these community water systems that add fluoride, PHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L). In this guidance, the optimal concentration of fluoride in drinking water is the concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier PHS recommendation for fluoride concentrations was based on outdoor air temperature of geographic areas and ranged from 0.7–1.2 mg/L. This updated guidance is intended to apply to community water systems that currently fluoridate or that will initiate fluoridation, and is based on considerations that include:

- Scientific evidence related to the effectiveness of water fluoridation in caries prevention and control across all age groups,
- Fluoride in drinking water as one of several available fluoride sources,
- Trends in the prevalence and severity of dental fluorosis, and
- Current evidence on fluid intake of children across various outdoor air temperatures.

**FOR FURTHER INFORMATION CONTACT:** Barbara F. Gooch, DMD, MPH, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, 4770 Buford Highway NE., MS F–80, Atlanta, GA 30341–3717; tel. 770–488–6054; fax 770–488–6080; email <*BGooch@cdc.gov*>.

**SUPPLEMENTARY INFORMATION:** Because fluoridation of public drinking water systems had been demonstrated as effective in reducing dental caries, the U.S. Public Health Service (PHS) provided recommendations regarding optimal fluoride concentrations in drinking water for community water systems in 1962 (U.S. DHEW, 1962). The U.S. Department of Health and Human Services (HHS) is releasing this updated PHS recommendation because of new data that address changes in the prevalence of dental fluorosis, the relationship between water intake and outdoor temperature in children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. Although PHS recommends community water fluoridation as an effective public health intervention, the decision to fluoridate water systems is made by state and local governments.

As of December 31, 2012, the Centers for Disease Control and Prevention (CDC) estimated that approximately 200 million people in the United States were served by 12,341 community water systems that added fluoride to water or

purchased water with added fluoride from other systems. For many years, nearly all of these fluoridated systems used fluoride concentrations ranging from 0.8 to 1.2 mg/L; fewer than 1% of these systems used a fluoride concentration at 0.7 mg/L (Unpublished data, Water Fluoridation Reporting System, CDC, 2010). When water systems that add fluoride implement the new PHS recommendation (0.7 mg/L), the fluoride concentration in these systems will be reduced by 0.1 to 0.5 mg/L and fluoride intake from water will decline among most people served by these systems.

It is expected that implementation of the new recommendation will lead to a reduction of approximately 25% (range: 12%–42%) in fluoride intake from drinking water alone and a reduction of approximately 14% (range: 5%–29%) in total fluoride intake. These estimates are based on intake among young children at the 90th percentile of drinking water intake for whom drinking water accounts for 40%–70% of total fluoride intake (U.S. EPA, 2010a). Furthermore, these estimates are based on a weighted mean fluoride concentration of 0.94 mg/L in systems that added fluoride (or purchased water from systems that added fluoride) in 2009 (Unpublished data, Water Fluoridation Reporting System, CDC, 2009). Community water systems that contain naturally occurring fluoride at concentrations greater than 0.7 mg/L (estimated to serve about 11 million people) will not be directly affected by the new PHS recommendation.

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) sets standards for drinking water quality (*42 U.S.C.* 300f *et seq.* (1974)). EPA is in the process of reviewing the maximum amount of fluoride allowed in drinking water. Upon completion of its review, EPA will determine if it is appropriate to revise the drinking water standard for fluoride. Currently, the enforceable standard is set at 4.0 mg/L to protect against severe skeletal fluorosis, a rare condition in the United States (NRC, 2006; U.S. EPA, 2010b). If the EPA determines that it is appropriate to revise the standard, any revisions could affect certain community water systems that have naturally occurring fluoride. More information about EPA's existing drinking water standards for fluoride can be found at: *http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm.*

**Recommendation**

For community water systems that add fluoride to their water, PHS recommends a fluoride concentration of 0.7 mg/L (parts per million [ppm]) to maintain caries prevention benefits and reduce the risk of dental fluorosis.

**Rationale**

*Importance of Community Water Fluoridation*

Community water fluoridation is a major factor responsible for the decline in prevalence (occurrence) and severity of dental caries (tooth decay) during the second half of the 20th century (CDC, 1999). For adolescents, the prevalence of dental caries in at least one permanent tooth (excluding third molars) decreased from 90% among those aged 12–17 years in the 1960's (Kelly JE, 1975) to 60% among those aged 12–19 years in 1999–2004 (Dye B, *et al.,* 2007); during that interval, the number of permanent teeth affected by dental caries (*i.e.,* decayed, missing and filled) declined from 6.2 to 2.6, respectively. Adults also have benefited from community water fluoridation; the average number of affected teeth decreased from 18 among 35- to 44-year-old adults in the 1960s to 10 among 35- to 49-year-old adults in 1999–2004 (Kelly JE, *et al.,* 1973; Dye B, *et al.,* 2007). Although data were not age-adjusted, age groups in the 1999–2004 survey used a higher upper age limit, and both caries prevalence and number of teeth affected increased with age; thus, these comparisons may underestimate caries decline over time.

Although there have been notable declines in tooth decay, it remains one of the most common chronic diseases of childhood (U.S. DHHS, 2000; Newacheck PW *et al.,* 2000). In 2009–2010, national survey data showed that untreated dental caries among children varied by race/ethnicity and federal poverty level. About one in four children living below 100% of the federal poverty level had untreated decay (Dye BA *et al.,* 2012). Untreated tooth decay can result in pain, school absences, and poorer school performance (Lewis C, *et al.,* 2010; Detty AMR, *et al.,* 2014; Jackson SL, *et al.,* 2011; Seirawan H, *et al.,* 2012).

Systematic reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity (McDonagh MS, *et al.,* 2000a; McDonagh MS, *et al.,* 2000b; Truman BI, *et al.,* 2002; ARCPOH 2006; Griffin SO, *et al.,* 2007; Yeung, 2008; CPSTF, 2013). Effects included significant increases in the proportion of children who were caries-free and significant reductions in the number of teeth or tooth surfaces with caries in both children and adults (McDonagh MS, *et al.,* 2000b; ARCPOH 2006; Griffin SO, *et al.,* 2007; Yeung, 2008; CPSTF, 2013). When analyses were limited to studies conducted after the introduction of other sources of fluoride, especially fluoride toothpaste, beneficial effects across the lifespan from community water fluoridation were still apparent (McDonagh MS, *et al.,* 2000b; Griffin SO, *et al.,* 2007; Slade, *et al.,* 2013).

Fluoride in saliva and dental plaque works to prevent dental caries primarily through topical remineralization of tooth surfaces (Koulourides T, 1990; Featherstone JDB, 1999). Consuming fluoridated water and beverages, and foods prepared or processed with fluoridated water, throughout the day maintains a low concentration of fluoride in saliva and plaque that enhances remineralization. Although other fluoride-containing products are available and contribute to the prevention and control of dental caries, community water fluoridation has been identified as the most cost-effective method of delivering fluoride to all members of the community regardless of age, educational attainment, or income level (CDC, 1999; Burt BA, 1989). Studies continue to find that community water fluoridation is cost-saving (Truman B, *et al.,* 2002; O'Connell JM, *et al.,* 2005; Campain AC, *et al.,* 2010; Cobiac LJ and Vos T, 2012).

*Trends in Availability of Fluoride Sources*

Community water fluoridation and fluoride toothpaste are the most common sources of non-dietary fluoride in the United States (CDC, 2001b). Community water fluoridation began in 1945, reaching 49% of the U.S. population by 1975 and 67% by 2012 (*http://www.cdc.gov/fluoridation/statistics/2012stats.htm; http://www.cdc.gov/nohss/FSGrowth_text.htm*). Toothpaste containing fluoride was first marketed in the United States in 1955 (USDHEW, 1980). By 1983, more than 90% of children and adolescents 5–19 years of age, and almost 70% of young children 2–4 years of age, reportedly used fluoride toothpaste (Ismail AI, *et al,* 1987). By 1986, more than 90% of young children 2–4 years of age also were reported to use fluoride toothpaste (NCHS, 1988). And by the 1990s, fluoride toothpaste accounted for more than 90 percent of the toothpaste market (Burt BA and Eklund SA, 2005). Other products that provide fluoride now include mouth rinses, dietary fluoride supplements, and professionally applied fluoride compounds. More detailed explanations

of these products are published elsewhere. (CDC, 2001b; ADA, 2006; USDHHS, 2010)

More information on major sources of ingested fluoride and their relative contributions to total fluoride exposure in the United States is presented in an EPA report (U.S. EPA 2010a). To protect the majority of the population, EPA uses the 90th percentile of drinking water intake for all age groups in calculating the relative contribution for each fluoride source. The EPA definition of ''drinking water'' includes tap water ingested alone or with beverages and certain foods reconstituted in the home. Among children aged 6 months to 14 years, drinking water accounts for 40%–70% of total fluoride intake; for adults, drinking water provides 60% of total fluoride intake. Toothpaste that has been swallowed inadvertently is estimated to account for about 20 percent of total fluoride intake in very young children (1–3 years of age) (U.S. EPA 2010a). Other major contributors to total daily fluoride intake are commercial beverages and solid foods.

*Dental Fluorosis*

Fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel called dental fluorosis. Changes range from barely visible lacy white markings in milder cases to pitting of the teeth in the rare, severe form. The period of possible risk for fluorosis in the permanent teeth, excluding the third molars, extends from birth through 8 years of age when the pre-eruptive maturation of tooth enamel is complete (CDC, 2001b; Massler M and Schour I, 1958; Avery, 1987). The risk for and severity of dental fluorosis depends on the amount, timing, frequency, and duration of the exposure (CDC, 2001b). When communities first began adding fluoride to their public water systems in 1945, drinking water and local foods and beverages prepared with fluoridated water were the primary sources of fluoride for most children (McClure FJ, 1943; U.S. EPA, 2010b). At that time, only a few systems fluoridated their water, minimizing the amount of fluoride contributed by processed water to commercial foods and beverages. Since the 1940s, other sources of ingested fluoride such as fluoride toothpaste (if swallowed) and dietary fluoride supplements have become available. Fluoride intake from these products, in addition to water, other beverages, and infant formula prepared with fluoridated water, have been associated with increased risk of dental fluorosis (Levy SL, *et al.,* 2010; Wong MCM, *et al.,* 2010; Ismail AI and Hasson H, 2008; Osuji OO *et al.,* 1988; Pendrys DG *et al.,* 1994; Pendrys DG and Katz RV 1989; Pendrys DG, 1995). Both the 1962 PHS recommendations and the current updated recommendation for fluoride concentration in community drinking water were set to achieve reduction in dental caries while minimizing the risk of dental fluorosis.

Results of two national surveys indicate that the prevalence of dental fluorosis has increased since the 1980s, but mostly in very mild or mild forms. Data on prevalence of dental fluorosis come from the National Health and Nutrition Examination Survey (NHANES), 1999–2004 (Beltrán-Aguilar ED, *et al.,* 2010a). NHANES assessed the prevalence and severity of dental fluorosis among people aged 6 to 49 years. Twenty-three percent (95% confidence interval [CI]: 20.1, 26.1) had dental fluorosis, of which the vast majority was very mild or mild. Approximately 2% (95% CI: 1.5, 2.5) of people had moderate dental fluorosis, and less than 1% (95% CI: 0.1, 0.4) had severe fluorosis. Prevalence of dental fluorosis that was very mild or greater was higher among young people and ranged from 41% (95% CI: 36.3, 44.9) among adolescents aged 12–15 years to 9% (95% CI: 6.1, 11.4) among adults, aged 40–49 years.

The prevalence and severity of dental fluorosis among 12- to 15-year-olds in 1999–2004 also were compared with estimates from the Oral Health of United States Children survey, 1986–1987 (USDHHS, 1989), which was the first national survey to include measures of dental fluorosis. Although these two national surveys differed in sampling and representation (household vs. schoolchildren), findings support the hypothesis that there was an increase in dental fluorosis that was very mild or greater during the time between the two surveys. In 1986–1987 and 1999–2004, the prevalence of dental fluorosis was 23% and 41%, respectively, among adolescents aged 12 to 15 years. (Beltrán-Aguilar ED, *et al.,* 2010a). Similarly, the prevalence of very mild fluorosis (17.2% and 28.5%), mild fluorosis (4.1% and 8.6%), and moderate and severe fluorosis combined (1.3% and 3.6%) among 12- to 15-year-old adolescents during 1986–1987 and 1999–2004, respectively, all showed increases. Estimates limited to severe fluorosis among adolescents in both surveys, however, were statistically unreliable because there were too few cases among survey participants examined. The higher prevalence of dental fluorosis in young people in 1999–2004 may reflect increases in fluoride exposures (intake) across the U.S. population.

Children are at risk for fluorosis in the permanent teeth from birth through 8 years of age. Adolescents who were 12–15 years of age when they participated in the national surveys of 1986–1987 and 1999–2004 would have been at risk for dental fluorosis from 1971–1983 and from 1984–2000, respectively.

By 1969, the percentage (number) of the U.S. population receiving fluoridated water was 44% (88,475,684). By 1985, this percentage (number) increased about 10 percentage points, reaching 55% (130,172,334). By 2000, this percentage (number) was 57% (161,924,080). Although the percentage point increases in more recent years appear small (2 percentage points from 1985 to 2000), it is important to note that the total size of the U.S. population also continued to expand during the time period. As a result, the 10-percentage-point increase from 1969 to 1985 reflects an increase of more than 40 million people receiving fluoridated water whereas the 2-percentage-point increase from 1985 to 2000 represents an increase of more than 30 million people.

Available data do not support additional detailed examination of changes in the percentage of children and adolescents using fluoride toothpaste. As previously described in Trends in Availability of Fluoride Sources, by 1983, more than 90% of children and adolescents, 5–19 years, and almost 70% of young children, 2–4 years of age, were reportedly using fluoride toothpaste (Ismail AI, *et al.,* 1987); by 1986 more than 90% of young children were also using fluoride toothpaste (NCHS, 1988). As mentioned, recent EPA estimates indicate that toothpaste swallowed inadvertently accounts for about 20 percent of total fluoride intake in very young children (U.S. EPA 2010a).

More information on fluoride concentrations in drinking water and the risk of severe dental fluorosis in children is presented in a report by EPA (U.S. EPA 2010b). EPA's scientific assessments considered new data on dental fluorosis and updated exposure estimates to reflect current conditions. Based on original data from a study that predated widespread water fluoridation in the United States, EPA determined that the benchmark dose for a 0.5% prevalence of severe dental fluorosis was a drinking water fluoride concentration of 2.14 mg/L, with a lower 95% CI of 1.87 mg/L (U.S. EPA 2010b). Categorical regression modeling (U.S. EPA, 2011 presentation) also indicated that the concentration of

fluoride in water associated with a 1% prevalence of severe dental fluorosis decreased over time (1940–2000). These findings are consistent with an increase in exposures from other sources of fluoride and support the conclusion that a fluoride concentration in drinking water of 0.7 mg F/L would reduce the chance of dental fluorosis—especially severe dental fluorosis—in the current context of multiple fluoride sources.

The two EPA assessments of fluoride (U.S. EPA, 2010a; U.S. EPA, 2010b) responded to earlier findings of the National Research Council (NRC) of the National Academies of Science (NRC, 2006). The NRC had reviewed new data on fluoride at EPA's request and in 2006 recommended that EPA update health and exposure assessments to consider all sources of fluoride and to take into account dental effects—specifically, pitting of teeth (*i.e.,* severe dental fluorosis) in children. The NRC identified severe dental fluorosis as an adverse health effect, because pitting of the enamel compromises its protective function. The NRC's report focused on the potential for adverse effects from naturally occurring fluoride at 2–4 mg/L in drinking water; it did not examine benefits or risks that might occur at lower concentrations typically used for community water fluoridation (0.7 to 1.2 mg/L) (NRC, 2006). For this PHS recommendation, Panel scientists did review the balance of benefits and potential for unwanted effects of water fluoridation at those lower levels (U.S. EPA, 2010b).

*Relationship Between Dental Caries and Fluorosis at Varying Water Fluoridation Concentrations*

The 1986–1987 Oral Health of United States Children survey has been the only national survey that assessed the child's water fluoride exposure, thus allowing linkage of that exposure to measures of caries and fluorosis (USDHHS, 1989). An additional analysis of data from this survey examined the relationship between dental caries and fluorosis at varying water fluoride concentrations for children and adolescents (Heller KE, *et al.,* 1997). Findings indicate that there was a gradual decline in dental caries as fluoride content in water increased from negligible to 0.7 mg/L. Reductions plateaued at concentrations from 0.7–1.2 mg/L. In contrast, the percentage of children with at least very mild dental fluorosis increased from 13.5% (standard error [SE] = 1.9) to 41.4% (SE = 4.4) as fluoride concentrations in water increased from <0.3 mg/L to >1.2 mg/L.

In Hong Kong, a small decrease of about 0.2 mg/L in the mean fluoride concentration in drinking water in 1978 (from 0.82 mg/L to 0.64 mg/L) was associated with a detectable reduction in fluorosis prevalence by the mid-1980s, from 64% (SE = 4.1) to 47% (SE = 4.5), based on the upper right central incisor only. Across all age groups, more than 90 percent of fluorosis cases were very mild or mild (Evans RW and Stamm JW, 1991). The study did not include measures of fluoride intake. Concurrently, dental caries prevalence did not increase (Lo ECM, *et al.,* 1990). Although not fully generalizable to the current U.S. context, these findings, along with findings from the 1986–1987 survey of U.S. schoolchildren, suggest that the risk of fluorosis can be reduced and caries prevention maintained toward the lower end (*i.e.,* 0.7 mg/L) of the 1962 PHS recommendations for community water fluoridation.

*Relationship of Water Intake and Outdoor Temperature Among Children and Adolescents in the United States*

The 1962 PHS recommendations stated that community drinking water should contain 0.7–1.2 mg/L (ppm) fluoride, depending on the outdoor air temperature of the area. These temperature-related guidelines were based on studies conducted in two communities in California in the early 1950s. Findings indicated that a lower fluoride concentration was appropriate for communities in warmer climates because children drank more water on warm days (Galagan DJ, 1953; Galagan DJ and Vermillion JR, 1957; Galagan DJ, *et al.,* 1957). Social and environmental changes, including increased use of air conditioning and more sedentary lifestyles, have occurred since the 1950s—thus, the assumption that children living in warmer regions drink more tap water than children in cooler regions may no longer be valid (Heller, *et al.,* 1999).

Studies conducted since 2001 suggest that children's water intake does not increase with increases in outdoor air temperature (Sohn W, *et al.,* 2001; Beltrán-Aguilar ED, *et al.,* 2010b). One study conducted among children using nationally representative data from NHANES 1988–1994 did not find an association between either total or plain water intake and outdoor air temperature (Sohn W, *et al.,* 2001). Although a similar study using nationally representative data from NHANES 1999–2004 also found no association between total water intake and outdoor temperature among children or adolescents (Beltrán-Aguilar ED, *et al.,* 2010b), additional analyses of these data detected a small but statistically significant association between plain water intake and outdoor temperature (Beltrán-Aguilar ED, *et al.,* manuscript for Public Health Reports). Temperature explained less than 1% of the variation in plain water intake; thus, these findings support use of one target concentration for community water fluoridation in all temperature zones of the United States, a standard far simpler to implement than the 1962 temperature-based recommendations. In these analyses, ''plain water'' was defined as from the tap or bottled water and ''total water'' included water from or mixed with other beverages, such as juice, soda, sport drinks, and non-dairy milk, as well as water from or mixed with foods (Beltrán-Aguilar ED, *et al.,* manuscript for Public Health Reports).

**Process**

HHS convened a federal inter-departmental, inter-agency panel of scientists (Appendix A) to review scientific evidence relevant to the 1962 PHS Drinking Water Standards for fluoride concentrations in drinking water in the United States and to update these recommendations based on current science. Panelists included representatives from the CDC, the National Institutes of Health, the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, the EPA, and the U.S. Department of Agriculture. The Panel evaluated recent systematic reviews of the effectiveness of fluoride in drinking water to prevent dental caries, as well as published reports about the epidemiology of dental caries and fluorosis in the United States and the relationship of these conditions with varying water fluoridation concentrations. The Panel also reviewed existing recommendations for fluoride in drinking water and newer data on the relationship between water intake in children and outdoor air temperature in the United States—a relationship that had served as the basis for the 1962 recommendation.

Recent systematic reviews of evidence on the effectiveness of community water fluoridation were from the Community Preventive Services Task Force (CPSTF), first published in 2001 and updated in 2013, and the Australian National Health and Medical Research Council in 2007 (Truman BI, *et al.,* 2002; CPSTF, 2013). Both reviews updated a comprehensive systematic review of water fluoridation completed by the National Health Service Centre for Reviews and Dissemination, University of York, in 2000 (McDonagh MS *et al.,*

2000a, McDonagh MS *et al.,* 2000b). In these reviews, estimates of fluoridation effectiveness in preventing caries were limited to children and adolescents and based on comparative studies. Random assignment of individuals usually is not feasible for studies of water fluoridation, because the intervention occurs in the community water system. Another systematic review examined the effectiveness of water fluoridation in preventing dental caries in adults. Findings were based primarily on cross-sectional studies of lifelong residents of communities with fluoridated or non-fluoridated water (Griffin SO, et al, 2007). Studies in these systematic reviews were not limited to the United States.

Panel scientists accepted an extensive review of fluoride in drinking water by the NRC (NRC, 2006) as the summary of hazard. The NRC review focused on potential adverse effects of naturally occurring fluoride at 2–4 mg/L in drinking water; it found no evidence substantial enough to support effects other than severe dental fluorosis at these levels. A majority of NRC Committee members also concluded that lifetime exposure to fluoride at a drinking water concentration of 4.0 mg/L (the enforceable standard established by EPA) is likely to increase bone fracture rates in the population, compared with exposures at 1.0 mg/L (NRC, 2006). Fluoride concentrations used for water fluoridation have been substantially lower than the enforceable standard EPA established to protect against severe skeletal fluorosis (USDHEW, 1962; NRC, 2006).

Conclusions of the Panel were summarized, along with their rationale, in the **Federal Register** document (USDHHS, 2011). PHS guidance is advisory, not regulatory, in nature.

*Overview of Public Comments:* The public comment period for the Proposed Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries lasted for 93 days; it began with publication of the **Federal Register** notice on January 13, 2011, and was extended from its original deadline of February 14, 2011, to April 15, 2011 to allow adequate time for interested organizations and members of the public to respond. Duplicate comments (*e.g.,* electronic and paper submissions from the same source) were counted as one comment. Although the 51 responses received electronically or postmarked after the deadline (midnight ET, April 15, 2011) were not reviewed, all other comments were considered carefully.

Approximately 19,300 responses were received; of these responses, approximately 18,500 (96 percent) were nearly identical to a letter submitted by an organization opposing community water fluoridation, often originating from the Web site of that organization; hereafter, these responses are called ''standard letters.'' Of the remaining 746 unique responses, 79 anecdotes described personal experiences, often citing potentially harmful effects, and 18 consisted of attachments only. Attachments to the unique submissions were examined to ensure that they addressed the recommendation, and to determine whether they supported it, opposed it as too low, or opposed it as too high. Although nearly all responses came from the general public, comments also were submitted by organizations, such as those representing dental, public health, or water supply professionals; those that advocate cessation of community water fluoridation; or commercial companies.

Of the unique responses, most opposed the recommendation as still too high and presented multiple concerns. Four CDC scientists (who did not serve on the inter-agency Federal Panel) reviewed all unique responses and used an electronic list of descriptors to categorize their contents. Comments were summarized and reported to the full Federal Panel, along with examples reflecting a range of differing opinions regarding the new recommendation. The following sections summarize frequent comments and provide the Federal Panel's response, divided into three categories: Comments that opposed the recommendation as still too high, comments that opposed the recommendation as too low to achieve prevention of dental caries, and comments that supported the recommendation. Data on the approximate numbers of comments received in support of and opposed to the new recommendation are provided for informational purposes. Responses to these comments are based primarily on conclusions of evidence-based reviews and/or expert panels that reviewed and evaluated the best available science.

## Comments That Opposed the Recommendation as Too High

Nearly all submissions opposed community water fluoridation at any concentration; they stated that the new recommendation remains too high, and most asked that all fluoride be removed from drinking water. These submissions include the standard letters (~18,500) and unique responses (~700 said the new level was too high; of these ~500 specifically asked for all fluoride to be removed). Nearly all of these submissions listed possible adverse health effects as concerns specifically, severe dental fluorosis, bone fractures, skeletal fluorosis, carcinogenicity, lowered IQ and other neurological effects, and endocrine disruption.

In response to these concerns, PHS again reviewed the scientific information cited to support actions announced in January 2011 by the HHS (U.S. DHHS, 2011) and the EPA (U.S. EPA, 2010a; U.S. EPA, 2010b)—and again considered carefully whether or not the proposed recommendations and standards on fluoride in drinking water continue to provide the health benefits of community water fluoridation while minimizing the chance of unwanted health effects from too much fluoride. After a thorough review of the comments opposing the recommendation, the Federal Panel did not identify compelling new information to alter its assessment that the recommended fluoride concentration (0.7 mg/L) provides the best balance of benefit to potential harm.

### *Dental Fluorosis*

The standard letters stated that the new recommendation would not eliminate dental fluorosis and cited its current prevalence among U.S. adolescents. In national surveys cited by the initial **Federal Register** notice, however, more than 90 percent of dental fluorosis in the United States is the very mild or mild form, most often appearing as barely visible lacy white markings or spots on the enamel (Beltrán-Aguilar, ED, *at al.,* 2010a). EPA considers the severe form of dental fluorosis, with staining and pitting of the tooth surface, as the ''adverse health effect'' to be prevented (U.S. EPA, 2010b). Severe dental fluorosis is rare in the United States, and its prevalence could not be estimated among adolescents in a national survey because there were too few cases among the survey participants examined to achieve statistical reliability (Beltrán-Aguilar, ED, et al, 2010a). The NRC review noted that prevalence of severe dental fluorosis was near zero at fluoride concentrations below 2 mg/L (NRC, 2006, p. 10). In addition, the most recent review of community water fluoridation by the Community Preventive Services Task Force concluded that ''there is no evidence that community water fluoridation results in severe dental fluorosis'' (CPSTF, 2013).

Standard letter submissions also expressed concern that infants fed formula reconstituted with fluoridated drinking water would receive too much fluoride. If an infant is consuming only

infant formula mixed with fluoridated water, there may be an increased chance for permanent teeth (when they erupt at ~ age 6) to have mild dental fluorosis (ADA, 2011). To lessen this chance, parents may choose to use low-fluoride bottled water some of the time to mix infant formula, *e.g.,* bottled waters labeled as de-ionized, purified, demineralized, or distilled, and without any fluoride added after purification treatment (FDA requires the label to indicate when fluoride is added). Such guidance currently is found on the Web sites of both CDC (*http://www.cdc.gov/fluoridation/safety/infant_formula.htm*) and the American Dental Association (*http://www.mouthhealthy.org/en/az-topics/f/fluorosis.aspx*). The PHS recommendation to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation, from birth through 8 years of age for most permanent teeth (CDC, 2001b; Avery, 1987; Massler M and Schour I, 1958), and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water.

*Bone Fractures and Skeletal Fluorosis*

Some unique comments (~100) cited fractures or other pathology of bone, while the standard letters expressed concern about skeletal fluorosis (*i.e.,* a bone disease caused by excessive fluoride intake for a long period of time that in advanced stages can cause pain or damage to bones and joints) and suggested that symptoms of stage II skeletal fluorosis (*i.e.,* a clinical stage associated with chronic pain) are identical to those of arthritis (*i.e.,* sporadic pain and stiffness of the joints). The NRC review found no recent studies to evaluate the prevalence of skeletal fluorosis in U.S. populations exposed to fluoride at the current maximum level of 4.0 mg/L (NRC, 2006). On the basis of existing epidemiologic literature, the NRC concluded that stage III skeletal fluorosis (*i.e.,* a clinical stage associated with significant bone or joint damage) ''appears to be a rare condition in the United States'' and stated that the committee ''could not determine whether stage II skeletal fluorosis is occurring in U.S. residents who drink water with fluoride at 4 mg/L'' (NRC, 2006).

The NRC also recommended that EPA consider additional long-term effects on bone in adults—stage II skeletal fluorosis and bone fractures—as well as the health endpoint that had been evaluated previously (*i.e.* stage III skeletal fluorosis) (NRC, 2006). In response, the EPA Dose-Response Analysis for Non-Cancer Effects noted that, although existing data were inadequate to model the relationship of fluoride exposure and its impact on bone strength, skeletal effects among adults are unlikely to occur at the fluoride intake level estimated to protect against severe dental fluorosis among children (U.S. EPA, 2010b). The EPA report concluded that exposure to concentrations of fluoride in drinking water of 4 mg/L and above appears to be positively associated with the increased relative risk of bone fractures in susceptible populations when compared with populations consuming fluoride concentrations of 1 mg/L (U.S. EPA, 2010b). Recently, a large cohort study of older adults in Sweden reported no association between long-term exposure to drinking water with fluoride concentrations up to 2.7 mg/L and hip fracture (Näsman P, *et al.,* 2013).

The fluoride intake estimated by EPA to protect against severe dental fluorosis among children during the critical period of enamel formation was determined to be ''likely also protective against fluoride-related adverse effects in adults, including skeletal fluorosis and an increased risk of bone fractures'' (U.S. EPA, 2010b). EPA compared its own risk assessments for skeletal effects with those made both by the NRC in 2006 and by the World Health Organization in 2002. EPA concluded that its own dose recommendation is protective compared with each of these other benchmarks and, thus, is ''applicable to the entire population since it is also protective for the endpoints of severe fluorosis of primary teeth, skeletal fluorosis, and increased risk of bone fractures in adults'' (U.S. EPA, 2010b).

*Carcinogenicity*

Some unique comments (~100) mentioned concerns regarding fluoride as a carcinogen, and the standard letters called attention to one study (Bassin, *et al.,* 2006) that reported an association between osteosarcoma (*i.e.,* a type of bone cancer) among young males and estimated fluoride exposure from drinking water, based on residence history. The study examined an initial set of cases from a hospital-based case-control study of osteosarcoma and fluoride exposure. Findings from subsequent cases (Kim, *et al.,* 2011) were published in 2011. This later study assessed fluoride exposure using actual bone fluoride concentration—a more accurate and objective measure than previous estimates based on reported fluoride concentrations in drinking water at locations in the reported residence history. The later study showed no significant association between bone fluoride levels and osteosarcoma risk (Kim, *et al.,* 2011). This finding is consistent with systematic reviews (McDonagh, 2000b; Parnell, 2009; ARCPOH, 2006, Yeung, 2008) and three recent ecological studies (Comber, *et al.,* 2011; Levy and Leclerc, 2012; Blakey K, *et al.,* 2014) that found no association between incidence of this rare cancer and the fluoride content of community water. Although study authors acknowledged the statistical and methodological limitations of ecological analyses, they also noted that their findings were consistent with the hypothesis that low concentrations of fluoride in water do not increase the risk of osteosarcoma development.

A critical review of fluoride and fluoridating agents of drinking water, accepted by the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) in 2010, used a weight-of-evidence approach and concluded that epidemiological studies did not indicate a clear link between fluoride in drinking water and osteosarcoma or cancer in general. In addition, the committee found that the available data from animal studies, in combination with the epidemiology results, did not support classifying fluoride as a carcinogen (SCHER, 2010). Finally, the Proposition 65 Carcinogen Identification Committee, convened by the Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, determined in 2011 that fluoride and its salts have not clearly been shown to cause cancer (OEHHA CA, 2011).

*IQ and Other Neurological Effects*

The standard letters and approximately 100 unique responses expressed concern about fluoride's impact on the brain, specifically citing lower IQ in children. Several Chinese studies (Xiang, *et al.,* 2003; Lu, *et al.,* 2000; Zhao, *et al.,* 1996) considered in detail by the NRC review reported lower IQ among children exposed to fluoride in drinking water at mean concentrations of 2.5–4.1 mg/L—several times higher than concentrations recommended for community water fluoridation. The NRC found that ''the significance of these Chinese studies is uncertain'' because important procedural details were omitted, but also stated that findings warranted additional research on the effects of fluoride on intelligence (NRC, 2006).

Based on animal studies, the NRC committee speculated about potential

mechanisms for nervous system changes and called for more research ''to clarify the effect of fluoride on brain chemistry and function'' (NRC, 2006). These recommendations should be considered in the context of the NRC review, which limited its conclusions regarding adverse effects to water fluoride concentrations of 2–4 mg/L and did ''not address the lower exposures commonly experienced by most U.S. citizens'' (NRC, 2006). A recent meta-analysis of studies conducted in rural China, including those considered by the NRC report, identified an association between high fluoride exposure (*i.e.,* drinking water concentrations ranging up to 11.5 mg/L) and lower IQ scores; study authors noted the low quality of included studies and the inability to rule out other explanations (Choi, *et al.,* 2012). A subsequent review cited this meta-analysis to support its identification of ''raised fluoride concentrations'' in drinking water as a developmental neurotoxicant (Grandjean and Landrigan, 2014).

A review by SCHER also considered the neurotoxicity of fluoride in water and determined that there was not enough evidence from well-controlled studies to conclude if fluoride in drinking water at concentrations used for community fluoridation might impair the IQ of children (SCHER, 2010). The review also noted that ''a biological plausibility for the link between fluoridated water and IQ has not been established'' (SCHER, 2010). Findings of a recent prospective study of a birth cohort in New Zealand did not support an association between fluoride exposure, including residence in an area with fluoridated water during early childhood, and IQ measured repeatedly during childhood and at age 38 years (Broadbent, *et al.,* 2014).

*Endocrine Disruption*

All of the standard letters and some of the unique comments (~100) expressed concern that fluoride disrupts endocrine system function, especially for young children or for individuals with high water intake. The 2006 NRC review considered a potential association between fluoride exposure (2–4 mg/L) and changes in the thyroid, parathyroid, and pineal glands in experimental animals and humans (NRC, 2006). The report noted that available studies of the effects of fluoride exposure on endocrine function have limitations. For example, many studies did not measure actual hormone concentrations, and several studies did not report nutritional status or other factors likely to confound findings. The NRC called for better measurement of exposure to fluoride in epidemiological studies and for further research ''to characterize the direct and indirect mechanisms of fluoride's action on the endocrine system and factors that determine the response, if any, in a given individual'' (NRC, 2006). A review did not find evidence that consuming drinking water with fluoride at the level used in community water fluoridation presents health risks for people with chronic kidney disease (Ludlow, *et al.,* 2007).

*Effectiveness of Community Water Fluoridation in Caries Prevention*

In addition to citing potential adverse health effects, the standard letters stated that the benefits of community water fluoridation have never been documented in any randomized controlled trial. There are no randomized, double-blind, controlled trials of water fluoridation because its community-wide nature does not permit randomization of individuals to study and control groups or blinding of participants. However, community trials have been conducted, and these studies were included in systematic reviews of the effectiveness of community water fluoridation (McDonagh, *et al.,* 2000b; Truman BI, *et al.,* 2002; CPSTF, 2013). As noted, these reviews of the scientific evidence related to fluoride have concluded that community water fluoridation is effective in decreasing dental caries prevalence and severity.

Standard letters also stated that African-American and low-income children would not be protected by the recommendation, as they have experienced more tooth decay than other racial/ethnic groups, despite exposure to fluoride through drinking water and other sources. Data from the NHANES (Dye B, *et al.,* 2007) do not support this statement and, instead, document a decline in the prevalence and severity of dental caries (tooth decay) across racial/ethnic groups. For example, in 1999–2004, compared with 1988–1994, the percentage of adolescents aged 12–19 years who had experienced dental caries in their permanent teeth, by race/ethnicity, was 54% in African-American (down from 63%), 58% in non-Hispanic white (down from 68%), and 64% in Mexican-American (down from 69%) adolescents (Dye B, *et al.,* 2007). For adolescents whose family income was less than 100% of the federal poverty level, a similar decline occurred: 66% had experienced dental caries in 1999–2004, down from 72% in 1988–1994. Although disparities in caries prevalence among these adolescent groups remain, the prevalence for each group was lower in 1999–2004 than in 1988–1994. Concurrent with these reductions in the prevalence of dental caries, the percentage (number) of the U.S. population receiving fluoridated water increased from 56% (144,217,476) in 1992 to 62% (180,632,481) in 2004 (*http://www.cdc.gov/nohss/fsgrowth.htm).* This change represented an increase of more than 36 million people.

*Cost-Effectiveness of Community Water Fluoridation*

Some unique comments (~200) called attention to the cost of water fluoridation or stated that it was unnecessary or inefficient given the availability of other fluoride modalities and the amount of water used for purposes other than drinking. Cost-effectiveness studies that included costs incurred in treating all community water with fluoride additives still found fluoridation to be cost-saving (Truman, *et al.,* 2002, Griffin, *et al.,* 2001). Although the annual per-person cost varies by size of the water system (from $0.50 in communities of 20,000 or more to $3.70 for communities of 5,000 or fewer, updated to 2010 dollars using the Consumer Price Index [CPI]), it remains only a fraction of the cost of one dental filling. The annual per person cost savings for those aged 6 to 65 years ranged from $35.90 to $28.70 for larger and smaller communities, respectively (Griffin, *et al.,* 2001, updated to 2010 dollars using CPI-dental services). Studies in the United States and Australia also have documented the cost-effectiveness of community water fluoridation (Truman BI, *et al.,* 2002; O'Connell JM *et al.,* 2005; Campain AC *et al.,* 2010; Cobiac LJ and Vos T, 2012).

*Safety of Fluoride Additives*

Unique comments (~300) expressed concern that fluoride is poison and an industrial waste product; standard letters noted the lack of specific data on the safety of silicofluoride compounds used by many water systems for community water fluoridation. All additives used to treat water, including those used for community water fluoridation, are subject to a system of standards, testing, and certification involving participation of the American Water Works Association, NSF International, and the American National Standards Institute (ANSI)—entities that are nonprofit, nongovernmental organizations. Most states require that water utilities use products that have been certified against *ANSI/NSF Standard 60: Drinking Water Treatment Chemicals—Health Effects*

(hereinafter, Standard 60) by an ANSI-accredited laboratory (U.S. EPA, 2000). All fluoride products evaluated against Standard 60 are tested to ensure that the levels of regulated impurities present in the product will not contribute to the treated drinking water more than 10% of the corresponding Maximum Contaminant Level (MCL) established by EPA for that contaminant (U.S. EPA, 2000). Results from 2000–2011, reported on the NSF International Web site (*http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf)* found that no contaminants exceeded the concentration allowed by Standard 60.

Although commenters expressed concerns about silicofluorides, studies have shown that these compounds achieve virtually complete dissolution and ionic disassociation at concentrations added to drinking water and thus, are comparable to the fluoride ion produced by other additives, such as sodium fluoride (Crosby, 1969; Finney, *et al;,* 2006, U.S. EPA, 2000). At the pH of drinking water, usually 6.5–8.5, and at a fluoride concentration of 1 mg/L, the degree of hydrolysis of hexafluorosilicic acid has been described as ''essentially 100%'' (U.S. EPA, 2000). Standard 60 provides criteria to develop an allowable concentration when no MCL has been established by the EPA. Using this protocol, NSF International calculations showed that a sodium fluorosilicate concentration needed to achieve 1.2 mg F/L would result in 0.8 mg/L of silicate, or about 5% of the allowable concentration calculated by NSF International. (*http://www.nsf.org/newsroom_pdf/NSF_Fact_Sheet_on_Fluoridation.pdf*).

SCHER also considered health and environmental risks associated with the use of silicofluoride compounds in community water fluoridation and concurred that in water they are rapidly hydrolyzed to fluoride, and that concentrations of contaminants in drinking water are well below guideline values established by the World Health Organization (SCHER, 2010).

*Ethics of Community Water Fluoridation*

All standard letters and some unique comments (~200) stated that water fluoridation is unethical mass medication of the population. To determine if a public health action that may encroach on individual preferences is ethical, a careful analysis of its benefits and risks must occur. In the case of water fluoridation, the literature offers clear evidence of its benefits in reducing dental decay (McDonagh MS, *et al.,* 2000a; McDonagh MS, *et al.,* 2000b; Truman BI, *et al.,* 2002; ARCPOH, 2006; Griffin SO, *et al.,* 2007; Yeung, 2008; CPSTF, 2013), with documented risk limited to dental fluorosis (U.S. EPA, 2010a; U.S. EPA, 2010b; McDonagh MS, *et al.,* 2000a; ARCPOH, 2006; CPSTF, 2013).

Several aspects of decision-making related to water fluoridation reflect careful analysis and lend support to viewing the measure as a sound public health intervention. State and local governments decide whether or not to implement water fluoridation, after considering evidence regarding its benefits and risks. Often, voters themselves make the final decision to adopt or retain community water fluoridation. Although technical support is available from HHS, federal agencies do not initiate efforts to fluoridate individual water systems. In addition, court systems in the United States have thoroughly reviewed legal challenges to community water fluoridation, and have viewed it as a proper means of furthering public health and welfare (*http://fluidlaw.org*).

**Comments That Opposed the Recommendation as Too Low**

Several unique comments said that 0.7mg/L is too low to offer adequate protection against tooth decay. Evidence, however, does suggest that 0.7 mg/L will maintain caries preventive benefits. Analysis of data from the 1986–1987 Oral Health of United States Children survey found that reductions in dental caries plateaued between 0.7–1.2 mg/L of fluoride (Heller KE *et al.,* 1997). In addition, fluoride in drinking water is only one of several available fluoride sources, such as toothpaste, mouth rinses, and professionally applied fluoride compounds.

**Comments That Supported the Recommendation**

Some submissions specifically endorsed lowering the concentration of fluoride in drinking water for the prevention of dental caries. Other commenters asked for guidance on the operational range for implementing the recommended concentration of 0.7 mg/L and on consistent messaging regarding the recommended change. Currently, CDC is reviewing available data and collaborating with organizations of water supply professionals to update operational guidance. In addition, CDC continues to support local and state infrastructure needed to implement and monitor the recommendation. Examples of this support include maintenance of the Water Fluoridation Reporting System; provision of training opportunities for water supply professionals; assisting state and local health agencies with health promotion and public education related to water fluoridation; and funding (in coordination with other Federal agencies, including the National Institute of Dental and Craniofacial Research) for research and surveillance activities related to dental caries, dental fluorosis, and fluoride intake.

**Monitoring Implementation of the New Recommendation**

Unpublished data from the Water Fluoridation Reporting System show how rapidly the proposed change in recommended concentration has gained acceptance. In December 2010, about 63% of the population on water systems adjusting fluoride (or buying water from such systems) was at 1.0 mg/L or greater and fewer than 1% at 0.7 mg/L. By summer 2011, only 6 months after publication of the draft notice, 68% of that population was at 0.7 mg/L and about 28% was at 1.0 mg/L or greater.

Following broad implementation of the new recommendation, enhanced surveillance during the next decade will detect changes in the prevalence and severity of dental caries and of dental fluorosis that is very mild or greater, nationally and for selected socio-demographic groups. For example, the 2011–2012 NHANES included clinical examination of children and adolescents by dentists to assess decayed, missing and filled teeth; presence of dental sealants; and dental fluorosis. The 2013–2014 examination added fluoride content of home water (assessed using water taken from a faucet in the home), residence history (needed to estimate fluoride content of home tap water for each child since birth), and questions on use of other fluoride modalities (*e.g.,* toothpaste, prescription drops, and tablets). As findings from these and future examinations become available, they can be accessed through the CDC Web site (*http://www.cdc.gov/nchs/nhanes/nhanes_products.htm*).

Definitive evaluation of changes in dental fluorosis prevalence or severity, associated with reduction in fluoride concentration in drinking water, cannot occur until permanent teeth erupt in the mouths of children who drank that water during the period of tooth development. HHS agencies continue to give priority to the development of valid and reliable measures of fluorosis, as well as technologies that could assess individual fluoride exposure precisely. A recent study documented the validity of fingernail fluoride concentrations at age 2–7 years as a biomarker for dental fluorosis of the permanent teeth at age 10–15 years (Buzalaf MA, *et al.,* 2012).

## Summary and Conclusions

PHS acknowledges the concerns of commenters and appreciates the efforts of all who submitted responses to the **Federal Register** notice describing its recommendation to lower the fluoride concentration in drinking water for the prevention of dental caries. The full Federal Panel considered these responses in the context of best available science but did not alter its recommendation that the optimal fluoride concentration in drinking water for prevention of dental caries in the United States should be reduced to 0.7 mg/L, from the previous range of 0.7–1.2 mg/L, based on the following information:

- Community water fluoridation remains an effective public health strategy for delivering fluoride to prevent tooth decay and is the most feasible and cost-effective strategy for reaching entire communities.
- In addition to drinking water, other sources of fluoride exposure have contributed to the prevention of dental caries and an increase in dental fluorosis prevalence.
- Caries preventive benefits can be achieved and the risk of dental fluorosis reduced at a fluoride concentration of 0.7 mg/L.
- Recent data do not show a convincing relationship between water intake and outdoor air temperature. Thus, recommendations for water fluoride concentrations that differ based on outdoor temperature are unnecessary.

Surveillance of dental caries, dental fluorosis, and fluoride intake will monitor changes that might occur, following implementation of the recommendation.

Dated: April 24, 2015.

**Sylvia M. Burwell,**

*Secretary.*

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## Appendix A—HHS Federal Panel on Community Water Fluoridation

Peter Briss, MD, MPH—Panel Chair, Medical Director, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

William Bailey, DDS, MPH (*former Panel member*), Acting Director (2011–2013), Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Laurie K. Barker, MSPH, Statistician, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Leila T. Beker, Ph.D., RD, Interdisciplinary Scientist, Infant Formula and Medical Foods Review Team, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services

Eugenio Beltrán-Aguilar, DMD, MPH, DrPH (*former Panel member*), Senior Epidemiologist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Mary Beth Bigley, DrPH, MSN, ANP (*former Panel member*), Acting Director, Office of Science and Communications, Office of the Surgeon General, U.S. Department of Health and Human Services

Linda Birnbaum, Ph.D., DABT, ATS, Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services

John Bucher, Ph.D., Associate Director, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services

Amit Chattopadhyay, PhD. *(former Panel member)*, Epidemiologist, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

Joyce Donohue, Ph.D., Health Scientist, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency

Elizabeth Doyle, Ph.D., Chief, Human Health Risk Assessment Branch, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency

Isabel Garcia, DDS, MPH, Deputy Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

Barbara Gooch, DMD, MPH, Associate Director for Science, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jesse Goodman, MD, MPH, Chief Scientist and Deputy Commissioner for Science and Public Health, Food and Drug Administration, U.S. Department of Health and Human Services

J. Nadine Gracia, MD, MSCE *(former Panel member)*, Chief Medical Officer (2009–2011), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Susan O. Griffin, Ph.D., Health Economist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Laurence Grummer-Strawn, Ph.D., Chief, Maternal and Child Nutrition Branch, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Jay Hirschman, MPH, CNS, Director, Special Nutrition Staff, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture

Frederick Hyman, DDS, MPH, Dental Officer, Division of Dermatology and Dental Products, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services

Timothy Iafolla, DMD, MPH, Supervisory Science Policy Analyst, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services

William Kohn, DDS *(former Panel member)*, Director (2010–11), Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Arlene M. Lester, DDS, MPH, CAPT, United States Public Health Service, Regional Minority Health Consultant, Office of the Secretary, US Department of Health and Human Services

Nicholas S. Makrides, DMD, MA, MPH, Assistant Surgeon General, Chief Dental Officer, United States Public Health Service, Chief Dentist, Federal Bureau of Prisons, U.S. Department of Justice

Richard Manski, DDS, MBA, Ph.D., Senior Scholar, Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services

Ana Maria Osorio, MD, MPH, Senior Advisor for the Public Health Service, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Benson Silverman, MD *(former panel member, deceased)*, Staff Director, Infant Formula and Medical Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services

Thomas Sinks, Ph.D., Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Meeting of the Presidential Commission for the Study of Bioethical Issues

**AGENCY:** Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues (the Commission) will conduct its twenty-first meeting on May 27, 2015. At this meeting, the Commission will discuss the role of deliberation and deliberative methods to engage the public and inform debate in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels.

**DATES:** The meeting will take place Wednesday, May 27, 2015, from 9 a.m. to approximately 5 p.m.

**ADDRESSES:** University of Pennsylvania Henry Jordan Medical Education Center, 5th Floor Lobby, 3400 Civic Center Boulevard, Philadelphia, PA 19104.

**FOR FURTHER INFORMATION CONTACT:** Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the twenty-first meeting of the Commission. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov.*

Under authority of E. O. 13521, dated November 24, 2009, the President established the Commission. The Commission is an expert panel of not more than 13 members who are drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. The Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda items for the Commission's twenty-first meeting are to discuss the role of deliberation and deliberative methods to engage the public and inform debate in bioethics, and how to integrate pubic dialogue into the bioethics conversation; bioethics education as a forum for fostering deliberative skills, and preparing students to participate in public dialogue in bioethics; goals and methods of bioethics education; and integrating bioethics education across a range of professional disciplines and educational levels. The draft meeting agenda and other information about the Commission, including information about access to the webcast, will be available at *www.bioethics.gov.*

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Dated: April 22, 2015.

**Lisa M. Lee,**

*Executive Director, Presidential Commission for the Study of Bioethical Issues.*

[FR Doc. 2015–10205 Filed 4–30–15; 8:45 am]

BILLING CODE 4154–06–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

*Date:* May 28–29, 2015.

*Time:* 9:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

*Contact Person:* Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov*.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Diet and Physical Activity Assessment.

*Date:* May 29, 2015.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

*Contact Person:* Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 24, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–10158 Filed 4–30–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Development of Radiation Modulators and Innovative Radiation Sources.

*Date:* May 11, 2015.

*Time:* 10:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W534, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Ivan Ding, Ph.D., Scientific Review Officer, 9609 Medical Center Drive, Room 7W534, Program & Review Extramural Staff Training Office, Division of Extramural Activities, National Cancer Institute, NIH, Bethesda, MD 20892–9750, (240) 276–6444, *dingi@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 27, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–10157 Filed 4–30–15; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; The Neuromuscular Junction and Aging.

*Date:* June 4, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC–9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 27, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–10155 Filed 4–30–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; 30-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIMH)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 5, 2015, Vol. 80, page 6521 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *NIMHprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIMH), 0925–0650, Expiration Date 1/31/2015, REINSTATEMENT WITHOUT CHANGE, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

*Need and Use of Information Collection:* There are no changes being requested for this submission. The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide information about the NIMH's customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the NIMH and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the NIMH's services will be unavailable.

The NIMH will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

*Request for Comments:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,408.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of collection | Number of respondents | Annual frequency per response | Hours per response | Total hours |
|---|---|---|---|---|
| **Estimated Annual Reporting Burden** | | | | |
| Conference/Training Pre- and Post-Surveys (various programs) | 3,000 | 1 | 30/60 | 1,500 |
| Surveys (electronic communications/outreach) | 25,000 | 1 | 5/60 | 2,083 |
| In-Depth Interviews | 50 | 1 | 90/60 | 75 |
| Focus groups and/or small discussion groups | 300 | 1 | 120/60 | 600 |
| Website and/or Software Usability Tests | 100 | 1 | 90/60 | 150 |
| Total | 28,450 | | | 4,408 |

Dated: April 27, 2015.

**Keisha L. Shropshire,**

*Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.*

[FR Doc. 2015–10232 Filed 4–30–15; 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 Initial Review Group; Behavior and Social Science of Aging Review Committee.

*Date:* June 2–3, 2015.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard Long Beach Downtown—Marriott, 500 E 1st Street, Long Beach, CA 90802.

*Contact Person:* Kimberly Firth, Ph.D., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, Md 20892, 301–402–7702, *kimberly.firth@nih.gov*.

*Name of Committee:* National Institute on Aging Initial Review Group; Neuroscience of Aging Review Committee, NIA N.

*Date:* June 4–5, 2015.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard Long Beach, 500 East First Street, Long Beach, CA 90815.

*Contact Person:* Jeannette L. Johnson, Deputy Review Branch Chief, National Institutes of Health, National Institute on Aging, Gateway Building, Bethesda, MD 20892, 301–402–7705, *johnsonj9@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 27, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–10156 Filed 4–30–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://beta.samhsa.gov/workplace.*

**FOR FURTHER INFORMATION CONTACT:** Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7–1051, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified

laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities: Gamma-Dynacare Medical Laboratories, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190

HHS-Certified Laboratories: ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400 (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023

Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840.

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370, (Formerly: SmithKline Beecham Clinical Laboratories)

Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

**Janine Denis Cook,**

*Chemist, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA.*

[FR Doc. 2015–10175 Filed 4–30–15; 8:45 am]

BILLING CODE 4160–20–P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[1651–0015]**

### Agency Information Collection Activities: Application for Extension of Bond for Temporary Importation

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

**ACTION:** 60-Day Notice and request for comments; extension of an existing collection of information.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Application for Extension of Bond for Temporary Importation (CBP Form 3173). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected on Form 3173. This document is published to obtain comments from the public and affected agencies.

**DATES:** Written comments should be received on or before June 30, 2015 to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10h Floor, Washington, DC 20229–1177.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

*Title:* Application for Extension of Bond for Temporary Importation.

*OMB Number:* 1651–0015.

*Form Number:* CBP Form 3173.

*Abstract:* Imported merchandise which is to remain in the customs territory for a period of one year or less without the payment of duties is entered as a temporary importation, as authorized under the Harmonized Tariff Schedules of the United States (19 U.S.C. 1202). When this time period is not sufficient, it may be extended by submitting an application on CBP Form 3173, ''*Application for Extension of Bond for Temporary Importation*''. This form is provided for by 19 CFR 10.37 and is accessible at: *http://www.cbp.gov/sites/default/files/documents/CBP%20Form%203173.pdf.*

*Current Actions:* CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to Form 3173.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses.

*Estimated Number of Respondents:* 1,200.

*Estimated Number of Annual Responses per Respondent:* 14.

*Estimated Total Annual Responses:* 16,800.

*Estimated Time per Response:* 13 minutes.

*Estimated Total Annual Burden Hours:* 3,646.

Dated: April 27, 2015.

**Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

[FR Doc. 2015–10255 Filed 4–30–15; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

### U.S. Customs and Border Protection 2015 West Coast Trade Symposium: ''Advancing Trade Through Partnership and Enforcement''

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security (DHS).

**ACTION:** Notice of Trade Symposium.

**SUMMARY:** This document announces that U.S. Customs and Border Protection (CBP) will convene the West Coast Trade Symposium in Tacoma, Washington on Wednesday, May 27, 2015. The West Coast Trade Symposium will feature panel discussions involving agency personnel, members of the trade community, and other government agencies, on the agency's role in international trade initiatives and programs. This marks CBP's fourteenth year convening the Trade Symposium. Members of the international trade and transportation communities and other interested parties are encouraged to attend.

**DATES:** Wednesday, May 27, 2015, (opening remarks and general sessions, 8:00 a.m.–5:30 p.m.).

**ADDRESSES:** The CBP 2015 West Coast Trade Symposium will be held at the Hotel Murano located at 1320 Broadway Plaza, Tacoma, Washington 98402.

**FOR FURTHER INFORMATION CONTACT:** The Office of Trade Relations at (202) 344–1440, or at *tradeevents@dhs.gov.* To obtain the latest information on the Trade Symposium and to register online, visit the CBP Web site at *http://www.cbp.gov/trade/stakeholder-engagement/trade-symposium.* Requests for special needs should be sent to the Office of Trade Relations at *tradeevents@dhs.gov.*

**SUPPLEMENTARY INFORMATION:** CBP will be holding two Trade Symposiums in 2015; one in Tacoma, Washington and one on the East Coast in the Washington, DC area later this year. Notice of and information regarding the 2015 East Coast Trade Symposium will be published at a later date. This document announces that CBP will convene the 2015 West Coast Trade Symposium on Wednesday, May 27, 2015. The theme for the 2015 West Coast Trade Symposium will be ''Advancing Trade Through Partnership and Enforcement.'' The format of the West Coast Trade Symposium will be held with general sessions. Discussions will be held regarding CBP's role in

international trade initiatives and partnerships.

The agenda for the 2015 West Coast Trade Symposium and the keynote speakers will be announced at a later date on the CBP Web site (*http://www.cbp.gov*). Registration is now open. The registration fee is $81.00 per person. Interested parties are requested to register early, as space is limited. All registrations must be made online at the CBP Web site (*http://www.cbp.gov/trade/stakeholder-engagement/trade-symposium*) and will be confirmed with payment by credit card only.

Due to the overwhelming interest to attend past symposiums, each company is requested to limit its company's registrations to no more than three participants in order to afford equal representation from all members of the international trade community. If a company exceeds the limitation, any additional names submitted for registration will automatically be placed on a waiting list.

Hotel accommodations will be announced at a later date on the CBP Web site (*http://www.cbp.gov*).

Dated: April 28, 2015.

**Maria Luisa Boyce,**

*Senior Advisor for Private Sector Engagement, Executive Director, Office of Trade Relations, Office of the Commissioner, U.S. Customs and Border Protection.*

[FR Doc. 2015–10256 Filed 4–30–15; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

### Accreditation and Approval of Atlantic Product Services, Inc., as a Commercial Gauger and Laboratory

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

**ACTION:** Notice of accreditation and approval of Atlantic Product Services, Inc., as a commercial gauger and laboratory.

**SUMMARY:** Notice is hereby given, pursuant to CBP regulations, that Atlantic Product Services, Inc., has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of October 29, 2014.

**DATES:** *Effective Dates:* The accreditation and approval of Atlantic Product Services, Inc., as commercial gauger and laboratory became effective on October 29, 2014. The next triennial inspection date will be scheduled for October 2017.

**FOR FURTHER INFORMATION CONTACT:** Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Atlantic Product Services, Inc., 2 Terminal Rd. KMI Bldg. OB2, Carteret, NJ 07008, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Atlantic Product Services, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

| API Chapters | Title |
|---|---|
| 3 | Tank gauging. |
| 7 | Temperature Determination. |
| 8 | Sampling. |
| 12 | Calculations. |
| 17 | Maritime Measurements. |

Atlantic Product Services, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

| CBPL No. | ASTM | Title |
|---|---|---|
| 27–05 | ASTM D–4928 | Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration. |
| 27–08 | ASTM D–86 | Standard Test Method for Distillation of Petroleum Products. |
| 27–11 | ASTM D–445 | Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of dynamic viscosity). |
| 27–14 | ASTM D–2622 | Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-ray Fluorescence Spectrometry. |
| 27–48 | ASTM D–4052 | Standard test method for density and relative density of liquids by digital density meter. |
| 27–50 | ASTM D–93 | Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester. |
| 27–53 | ASTM D–2709 | Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge. |
| 27–58 | ASTM D–5191 | Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method). |
| N/A | ASTM D–3606 | Determination of Benzene and Toluene in Finished Motor and Aviation Gasoline by Gas Chromatography. |
| N/A | ASTM D 5769 | Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry. |

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/sites/default/files/documents/gaulist_3.pdf.*

Dated: April 24, 2015.

**Ira S. Reese,**

*Executive Director, Laboratories and Scientific Services Directorate.*

[FR Doc. 2015–10257 Filed 4–30–15; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5828–N–18]**

### Federal Property Suitable as Facilities to Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by

HUD for suitability for use to assist the homeless.

**FOR FURTHER INFORMATION CONTACT:** Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

**SUPPLEMENTARY INFORMATION:** In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301)-443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720–8873; AIR FORCE: Mr. Robert E. Moriarty, P.E., AFCEC/CI, 2261 Hughes Avenue, Ste. 155, JBSA Lackland TX 78236–9853; ARMY: Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571) 256–8145; COE: Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street NW., Washington, DC 20314; (202) 761–5542; Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2703 Martin Luther King Jr. Ave. SE., Stop 7714, Washington, DC 20593–; (202) 475–5609; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 3960 N. 56th Ave. #104, Hollywood, FL 33021; (443) 223–4639; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management; Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: April 23, 2015.

**Brian P. Fitzmaurice,**

*Director, Division of Community Assistance, Office of Special Needs Assistance Programs.*

**TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 05/01/2015**

**Suitable/Available Properties**

*Building*

Alaska

Building 141
Hdqts. Area, Denali Nat'l Preserve
Denali Park AK 99755
Landholding Agency: Interior
Property Number: 61201520002
Status: Unutilized
Comments: 57+yrs.old; 1,042 sq. ft.; 12+mos. vacant; poor condition; storage; temp. foundation; roof needs to be replaced; contact Interior for more information.

California

Stonyford Modular Barracks
5171 Stonyford—Elk Creek Rd.
Stonyford CA 95979
Landholding Agency: Agriculture
Property Number: 15201520002
Status: Unutilized
Comments: off-site removal only; 42+yrs. old; 720 sq. ft.; residential; floors need replacing; no future agency need; prior approval to gain access is required; contact Agriculture for more information.

Ditchrider House in Tulelake
2717 Havlina Road
Tulelake CA 96134
Landholding Agency: Interior
Property Number: 61201520001
Status: Unutilized
Directions: District Parking Lot
Comments: 80+yrs. old; 480 sq.; residential; vacant 60+mos.; roof in disrepair; contact Interior for more information.

Michigan

Mio 4 Carpet Connection
Consumers Lease Cabin
Huron National Forest
Grayling MI
Landholding Agency: Agriculture
Property Number: 15201520009
Status: Unutilized
Comments: off site removal only; no future agency need; 1,600 sq. ft.; residential seasonal; cabin floor rotting/soft;

significant mold present; contact Agriculture for more information.

Utah

Little Mountain Communication
40.53807749–109.69935286
Maeser UT 84078
Landholding Agency: GSA
Property Number: 54201520002
Status: Excess
GSA Number: 7–A–UT–0536–AA
Directions: Disposal Agency: GSA, Land Holding Agency: Agriculture
Comments: off-site removal; 190 sq. ft.; 12+mos. vacant; radio tower, commercial; contact Forest Service to gain access; contact Agriculture for more information.

Vermont

Old Operators Quarters/USACE N
100 Reservoir Road
Springfield VT 05156
Landholding Agency: COE
Property Number: 31201520001
Status: Underutilized
Comments: off-site removal only; 50+yrs. old; 700 sq. ft.; storage; asbestos; no future agency need; contact COE for more information.

Washington

Building 03932
Joint Base Lewis McChord
JBLM WA 98433
Landholding Agency: Army
Property Number: 21201520001
Status: Underutilized
Comments: off-site removal only; no future agency need; 120 sq. ft.; storage; 49+ yrs.; significant repairs for restoration; contamination; contact Army for accessibility and removal requirements.

*Land*

Colorado

Grand Valley Project
39.25326873–108.84370271
Unincorporated CO 81524
Landholding Agency: GSA
Property Number: 54201520001
Status: Excess
GSA Number: 7–I–CO–0699–AA
Directions: Disposal Agency: GSA, Land Holding Agency: Interior
Comments: 30.12 acres; agricultural; silage pits; contact Interior for more information.

**Unsuitable Properties**

*Building*

Massachusetts

Building 181
181 East Road
Otis ANGB MA 02542
Landholding Agency: Air Force
Property Number: 18201520001
Status: Excess
Comments: public access denied & no alternative method to gain access without compromising National Security.
Reasons: Secured Area

3 Buildings
Otis ANGB, MA
Otis ANGB MA 02542
Landholding Agency: Air Force
Property Number: 18201510045
Status: Excess
Directions: Building 120; 122; 153
Comments: public access denied & no alternative method to gain access w/out compromising National Security.; property located within an Airport Runway Clear Zone.
Reasons: Secured Area; Within airport runway clear zone

Alaska

Duplex Housing Units 100 & 102
Lots 3 & 4, Block 2, Bettles Airport Subdivision
Bettles AK 99755
Landholding Agency: Interior
Property Number: 61201520003
Status: Unutilized
Comments: Property located within an airport runway.
Reasons: Within airport runway clear zone

Michigan

Mio 7 Winowiecki Consumers Cab
Huron Nat'l Forest Old M–72
(Smith Bridge)
Grayling MI 49738
Landholding Agency: Agriculture
Property Number: 15201520003
Status: Unutilized
Comments: documented deficiencies: documentation provided represents a clear threat to personal safety; significant rot in floor/roof structure; relocation will most likely result in the roof collapsing.
Reasons: Extensive deterioration

Mio 7 Winowiecki Consumers Lea
Huron National Forest Old M–72
(Smith Bridge)
Grayling MI 49738
Landholding Agency: Agriculture
Property Number: 15201520004
Status: Unutilized
Comments: documented deficiencies: documentation provided represents a clear threat to personal safety; interior space of the structure cannot be made to comply w/ habitability requirements.
Reasons: Extensive deterioration

Washington

Navy Reserve Center-Building 7
5101 N. Assemble Street
Spokane WA 99205
Landholding Agency: Navy
Property Number: 77201520002
Status: Excess
Comments: Public access denied & no alternative method to gain access without compromising National Security.
Reasons: Secured Area

*Land*

Georgia

Proposed Photovoltaic (PV) Sit
Marine Corps Logistics Base
Albany GA 31704
Landholding Agency: Navy
Property Number: 77201520001
Status: Underutilized
Comments: Public access denied & no alternative method to gain access without compromising National Security.
Reasons: Secured Area

[FR Doc. 2015–10017 Filed 4–30–15; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS–R8–MB–2015–N062; FF08M00000–FXMB12310800000–145]**

### Draft Environmental Impact Statement and Proposed Pacific Gas & Electric Company Eagle Conservation Plan

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

**ACTION:** Notice of intent to prepare an environmental impact statement; notice of scoping meeting and request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), intend to prepare a draft environmental impact statement (EIS) for the Pacific Gas and Electric Company's (PG&E) (Applicant) proposed Eagle Conservation Plan (ECP) and request for a 30-year programmatic eagle take permit for take of bald eagles and golden eagles under the Bald and Golden Eagle Protection Act (Eagle Act). The ECP, which serves as the foundation of the permit application, is a comprehensive plan that addresses take of the eagles associated with PG&E's existing infrastructure and operations and maintenance (O&M) activities throughout the Plan Area, which encompasses about two-thirds of the State of California. We provide this notice to (1) describe the proposed action; (2) advise other Federal and state agencies, potentially affected tribal interests, and the public of our intent to prepare an EIS; (3) announce the initiation of a 60-day public scoping period; and (4) obtain suggestions and information on the scope of issues and possible alternatives to be included in the EIS. We also announce plans for a public scoping meeting and the opening of a public comment period. We request data, comments, new information, or suggestions from the public, governmental agencies, the scientific community, tribes, industry, or any other interested party.

**DATES:** To ensure consideration, please send your written comments by June 30, 2015. A public scoping meeting will be held on May 21, 2015, at Red Lion Hotel Woodlake Conference Center, 500 Leisure Lane, Sacramento, CA 95815.

**ADDRESSES:** To request further information or submit written comments, please use one of the following methods, and note that your information request or comment is in reference to the PG&E Eagle Conservation Plan EIS:

- *Email:* [*fw8_eagle_nepa@fws.gov*]. Include ''PG&E Eagle Conservation Plan EIS'' in the subject line of the message.

- *U.S. Mail:* Heather Beeler, Migratory Bird Program, U.S. Fish and Wildlife Service, Pacific Southwest Regional Office, 2800 Cottage Way, W–2605, Sacramento, CA 95825.
- *Fax:* Heather Beeler, Migratory Bird Program, (916) 414–6486; Attn: PG&E Eagle Conservation Plan EIS Scoping.

**FOR FURTHER INFORMATION CONTACT:** Heather Beeler, Migratory Bird Program, at the address shown above or at (916) 414–6651 (telephone). If you use a telecommunications device for the deaf, please call the Federal Information Relay Service at (800) 877–8339.

**SUPPLEMENTARY INFORMATION:** We, the U.S. Fish and Wildlife Service (Service), intend to prepare a draft environmental impact statement (EIS) for the Pacific Gas and Electric Company's (PG&E) (Applicant) proposed Eagle Conservation Plan (ECP) and request for a 30-year programmatic eagle take permit under the Bald and Golden Eagle Protection Act (Eagle Act). The ECP serves as the foundation of the permit application. The ECP summarizes the applicant's current voluntary approach to address eagle and bird impacts associated with PG&E's existing infrastructure and operations and maintenance (O&M) activities throughout their ECP Plan Area (Plan Area).

The ECP is a comprehensive plan that addresses the take of bald eagles (*Haliaeetus leucocephalus*) and golden eagles (*Aquila chrysaetos*) associated with PG&E's existing infrastructure and O&M activities throughout the Plan Area, which encompasses about two-thirds of the State of California. The ECP also provides measures to avoid, minimize, and mitigate for eagle mortality. The draft EIS will evaluate the impacts of several alternatives related to the proposed issuance of a programmatic eagle take permit to PG&E for bald and golden eagles that results from system-wide standard O&M at their infrastructure and facilities.

We provide this notice to (1) describe the proposed action; (2) advise other Federal and state agencies, potentially affected tribal interests, and the public of our intent to prepare an EIS; (3) announce the initiation of a 60-day public scoping period; and (4) obtain suggestions and information on the scope of issues and possible alternatives to be included in the EIS.

We also announce plans for a public scoping meeting and the opening of a public comment period. We request data, comments, new information, or suggestions from the public, governmental agencies, the scientific community, tribes, industry, or any other interested party.

We publish this notice in accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321–4347, *et seq.;* NEPA), and its implementing regulations in the Code of Federal Regulations (CFR) at 40 CFR 1500–1508 as well as Section 668a of the Eagle Act (16 U.S.C. 668a–668d).

## Introduction

The Service is considering an application from PG&E, under the Eagle Act, for a 30-year programmatic take permit for bald and golden eagles. PG&E has prepared an ECP, which addresses incidental take of bald and golden eagles from electrocution and collision with above-ground electric transmission and distribution lines (collectively power lines), as well as disturbance of nesting eagles during various operations and maintenance (O&M) activities within the Plan Area. The Plan Area encompasses PG&E's Service Area including all electric and hydroelectric facilities located within the state of California. The ECP analyzes their system's risk to eagles. It also identifies measures to avoid, minimize and mitigate eagle mortality associated with those activities. The Plan Area is within the following California Counties:

Alameda
Alpine
Amador
Butte
Calaveras
Colusa
Contra Costa
Del Norte
El Dorado
Fresno
Glenn
Humboldt
Inyo
Kern
Kings
Lake
Lassen
Los Angeles
Madera
Marin
Mariposa
Mendocino
Merced
Modoc
Mono
Monterey
Napa
Nevada
Placer
Plumas
Sacramento
San Benito
San Bernardino
San Francisco
San Joaquin
San Luis Obispo
San Mateo
Santa Barbara
Santa Clara
Santa Cruz
Shasta
Sierra
Siskiyou
Solano
Sonoma
Stanislaus
Sutter
Tehama
Trinity
Tulare
Tuolumne
Ventura
Yolo
Yuba

## Background

Eagles are protected under the Eagle Act, which prohibits take and disturbance of individuals and nests. *Take* under the Eagle Act includes any actions that pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, destroy, molest, and disturb eagles. Disturb is further defined in 50 CFR 22.3 as ''to agitate or bother a bald or golden eagle to a degree that causes, or is likely to cause, based on the best scientific information available (1) injury to an eagle, (2) a decrease in its productivity, by substantially interfering with normal breeding, feeding, or sheltering behavior, or (3) nest abandonment, by substantially interfering with normal breeding, feeding, or sheltering behavior.''

Prior to 2009, permits for purposeful take of birds or body parts were limited to scientific (50 CFR 22.21), religious (50 CFR 22.22), or falconry (50 CFR 22.24) pursuits; for eagles causing serious injury to livestock or other wildlife (50 CFR 22.23); and for golden eagle nests that interfere with resource development or recovery operations (50 CFR 22.21–25). In 2009, we issued the *Final Rule for Eagle Permits; Take Necessary to Protect Interests in Particular Localities* (2009 Final Rule) on new permit regulations that allow take ''for the protection of . . . other interests in any particular locality'' and where the take is ''associated with and not the purpose of an otherwise lawful activity . . .'' (September 11, 2009; 74 FR 46836–46879). The 2009 Final Rule authorizes programmatic take (take that is recurring and not in a specific, identifiable timeframe and/or location) of eagles only if avoidance measures have been implemented to the maximum extent achievable. PG&E's activities are programmatic and existed prior to the 2009 Final Rule. Considerations for issuing take permits

include the health of the local and regional eagle populations, availability of suitable nesting and foraging habitat for any displaced eagles, and whether the take and associated mitigation provide a net benefit to eagles (74 FR 46836–46879). The programmatic take permit under the 2009 Final Rule was valid up to 5 years. In 2012, we proposed to extend the maximum term for programmatic take permits from 5 to 30 years (April 13, 2012; 77 FR 22267–22278), and in 2013, we issued a Final Rule to extend the maximum term for programmatic eagle permits to 30 years, subject to a recurring 5-year review process throughout the life of the permit (December 9, 2013; 78 FR 73704–78725).

PG&E's power lines have resulted in eagle mortality due to electrocution and collision. Furthermore, infrastructure associated with electric and hydroelectric energy generation requires long-term O&M, pipeline, and utility line modernization and replacement to produce and deliver reliable and safe energy to PG&E customers. Some O&M activities occur in eagle nesting habitat where there is a potential to disturb nesting eagles.

## Scope of EIS

PG&E's ECP serves as the foundation of the permit application. As such, all alternatives considered in the EIS should conform to the permit issuance criteria for programmatic eagle take permits under the Eagle Act as required in 50 CFR 22.26(f)(1–6).

The draft EIS will identify and analyze direct, indirect, and cumulative impacts of the proposed action and alternatives to several resource areas, including biological resources, public utilities, air quality, noise, water resources, cultural resources, socioeconomics, and climate change. We will also consider evaluation of additional resource areas if issues of concern specific to the proposed action are identified during the public scoping process. The purpose of the public scoping process for the EIS is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EIS. We will evaluate a minimum of three alternatives.

## Applicant's Proposal

PG&E has requested a programmatic eagle take permit for incidental take of bald and golden eagles associated with O&M activities in the Plan Area, as described in the ECP, for a term of 30 years. Specific activities covered under the ECP would include otherwise lawful activities that have the potential to kill eagles or disturb them to the extent that nests are abandoned or eagle productivity is decreased, as well as avoidance and minimization measures to reduce these impacts. The ECP describes:

(1) Eagle collision with or electrocution by PG&E's existing distribution and transmission lines and conductors within the Plan Area;

(2) Operation and maintenance of PG&E's electrical system, including inspection and patrols (aerial and ground), routine maintenance and repair, vegetation management (including tree pruning and removal with the right of way), and replacement or upgrades of existing power lines and infrastructure. This activity would apply to all power lines in the Plan Area (141,200 miles of distribution lines and 18,600 miles of transmission lines) and related infrastructure;

(3) Operation and maintenance of PG&E's hydroelectric system, including the associated electric system, recreation facility maintenance, log boom/buoy/safety marker maintenance, intake tunnel clearing, and repair of weirs and gages. This activity would apply to all facilities in the Plan Area, including 68 existing powerhouses, a pumped storage facility, and nearly 100 reservoirs;

(4) Continued implementation of migratory bird and eagle take-reduction measures, including, but not limited to:

(a) Adoption of avian-safe construction design standards;

(b) Proactive and reactive bird-safe power pole retrofits;

(c) Bird nest protection best management practices during vegetation management activities and other routine or project work;

(d) Bird flight diverter effectiveness studies;

(e) Targeted management at hydroelectric facilities; and

(f) Pre-construction nesting bird surveys when required for project work.

(5) Monitoring to validate the estimated amount of disturbance take and the number of fatalities associated with PG&E's existing infrastructure and to evaluate the effectiveness of the conservation measures at reducing eagle take. Monitoring efforts would generally include:

(a) Monitoring of eagle nests located throughout PG&E's hydroelectric system, as well as those discovered during inspections, patrols, and vegetation management activities; and

(b) Monitoring eagle fatalities during inspections, patrols, and vegetation management actions.

## Public Comments

We request data, comments, new information, or suggestions from the public, other governmental agencies, the scientific community, Tribes, industry, or any other interested party on this notice. We will consider these comments in developing the draft EIS.

## Public Availability of Comments

You may submit your comments and materials by one of the methods listed above in **ADDRESSES**. Before including your address, phone number, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—might 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.

## Scoping Meetings

See **DATES** for the date(s) and time(s) of our public meeting(s). The primary purpose of these meetings and public comment period is to provide the public with a general understanding of the background of the proposed action and to solicit suggestions and information on the scope of issues and alternatives we should consider when drafting the EIS. Oral and written comments will be accepted at the meetings. An interpreter and/or court reporter will be present when deemed necessary. Comments can also be submitted by methods listed in the **ADDRESSES** section. Once the draft EIS and proposed ECP are complete and made available for review, there will be additional opportunity for public comment on the content of these documents.

Persons needing reasonable accommodations in order to attend and participate in the public meetings should contact the Pacific Southwest Region's Migratory Bird Office using one of the methods listed above in **ADDRESSES** as soon as possible. In order to allow sufficient time to process requests, please make contact no later than one week before the public meeting. Information regarding this proposed action is available in alternative formats upon request.

## Authority

We provide this notice under section 668a of the Eagle Act (16 U.S.C. 668–668c) and NEPA regulations (40 CFR 1501.7, 40 CFR 1506.6, and 40 CFR 1508.22).

Dated: April 23, 2015.

**Alexandra Pitts,**

*Deputy Regional Director, Pacific Southwest Region, Sacramento, California.*

[FR Doc. 2015–10067 Filed 4–30–15; 8:45 am]

**BILLING CODE 4310–55–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS–R4–R–2014–N198; FXRS12650400000S3–123–FF04R02000]**

### Cat Island National Wildlife Refuge, Louisiana; Draft Comprehensive Conservation Plan and Environmental Assessment

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

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** We, the Fish and Wildlife Service (Service), announce the availability of a ''Draft Comprehensive Conservation Plan and Environmental Assessment (Draft CCP/EA) for Cat Island National Wildlife Refuge in West Feliciana Parish, Louisiana, for public review and comment. In this Draft CCP/EA, we describe the alternative we propose to use to manage this refuge for the 15 years following approval of the final CCP.

**DATES:** To ensure consideration, we must receive your written comments by June 1, 2015.

**ADDRESSES:** You may obtain a copy of the Draft CCP/EA by contacting Kent Ozment, Wildlife Refuge Specialist, U.S. Fish and Wildlife Service, Lower Mississippi River Refuge Complex, 21 Pintail Ln. 89, Natchez, MS 39165. Alternatively, you may download the document from our Internet site at *http://southeast.fws.gov/planning* under ''Draft CCP Documents.'' Comments on the Draft CCP/EA may be submitted to the above postal address or by email to Kent Ozment at *Kent_Ozment@fws.gov.*

**FOR FURTHER INFORMATION CONTACT:** Kent Ozment, Natural Resource Planner, (601) 442–6696 or *Kent_Ozment@fws.gov.*

**SUPPLEMENTARY INFORMATION:** With this notice, we continue the CCP process for Cat Island National Wildlife Refuge (NWR) started through a notice in the **Federal Register** on October 22, 2013 (78 FR 62648). For more about the refuge and our CCP process, please see that notice.

Cat Island National Wildlife Refuge was established in October 2000, as the 526th refuge in the National Wildlife Refuge System. It is located in West Feliciana Parish, Louisiana, near the town of St. Francisville, 25 miles north of Baton Rouge. The refuge currently encompasses 10,473 acres of bottomland hardwood forest, baldcypress-tupelo swamp, and shrub-scrub swamps. The Congressionally approved acquisition boundary encloses 36,500 acres.

Cat Island NWR is part of the Lower Mississippi River Ecosystem and is located on the southeastern edge of the Mississippi Alluvial Valley (MAV) Bird Conservation Region, which is incorporated into the Gulf Coastal Plans and Ozarks Landscape Conservation Cooperative. The refuge provides high-quality habitat for many species of waterfowl, wading birds, Neotropical migratory songbirds, and resident game and fish, as well as threatened and endangered species and species of concern. The refuge contains a number of relict old-growth baldcypress trees, including the world's largest known individual of this species.

#### Background

*The CCP Process*

The National Wildlife Refuge System Improvement Act of 1997 (Improvement Act), requires us to develop a CCP for each national wildlife refuge. CCPs are developed to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Improvement Act.

Priority resource issues addressed in the Draft CCP/EA include: Fish and Wildlife Population Management, Habitat Management, Resource Protection, Visitor Services, and Refuge Administration.

#### CCP Alternatives, Including Our Proposed Alternative (B)

We developed three alternatives for managing the refuge (Alternatives A, B, and C), with Alternative B as our proposed alternative. A full description of each alternative is in the Draft CCP/EA. We summarize each alternative below.

*Alternative A: Current Management (No Action)*

Under alternative A, Cat Island NWR would be managed as it has been in recent years. No new actions would be taken to manage Cat Island NWR, or improve or otherwise change the refuge's habitats, wildlife, or public use. Programs that have been ongoing in the past would continue. Certain monitoring activities would continue, including periodic migratory bird surveys. Maintenance of roads and public-use facilities would continue as presently conducted. Habitats would continue to be mostly passively managed, with actions taken only to provide for public safety or to avoid or mitigate damage to refuge resources. Current partnerships with the West Feliciana Parish Tourist Commission, Louisiana Hiking Club, Louisiana Department of Wildlife and Fisheries, and others would continue as before. The refuge hunting, fishing, and non-consumptive uses would continue as presently constituted. Legal requirements for protection of natural and cultural resources would continue to be met.

Acquisition of lands within the approved acquisition boundary would continue as before, contingent upon the availability of funding and appropriate lands offered by willing sellers. Law enforcement would continue to be a shared responsibility between the Service, the State of Louisiana, and the West Feliciana Parish Sheriff's Office. The refuge would continue to be unstaffed, and funding for its operation would be restricted to funds generated by the sale of recreational use permits and occasional special project funding.

*Alternative B: Active Resource Management (Proposed Alternative)*

Under this alternative, the refuge's natural resources would be managed to enhance habitats for priority species, including waterfowl and other migratory birds, threatened and endangered species, species of concern, and resident fish and wildlife. Additionally, consistent wildlife surveys would be conducted, using established protocols to establish baseline habitat conditions, estimate wildlife population indices, determine responses to management actions, and contribute to larger scale biological assessments. Invasive exotic and nuisance species would be actively managed to minimize their impacts on refuge resources. The refuge forests would be actively managed to enhance wildlife habitat. Aquatic habitats on the refuge would be inventoried and

assessed and, where feasible, access to them would be improved for recreational anglers.

The refuge cultural resources would continue to be protected as they have been in the past. In addition, the refuge would seek funding to survey and catalog cultural resources on the refuge. Protection of cultural resources would be integrated into refuge planning at all levels, and management actions would be reviewed in order to avoid or mitigate impacts to cultural resources.

Under the proposed alternative, public use would be more actively managed by refuge staff. Hunting and fishing would continue to be managed and made available with the active partnership of the Louisiana Department of Wildlife and Fisheries. More law enforcement personnel hours would be allocated by the Service for Cat Island NWR. New partnerships with organizations interested in promoting non-consumptive refuge use would be sought, and existing ones strengthened. In particular, environmental education opportunities would be enhanced by active participation of Service personnel with local schools and nonprofit organizations.

As under alternative A, acquisition of lands within the approved acquisition boundary would continue as before under the proposed alternative, contingent upon the availability of funding and appropriate lands offered by willing sellers. The refuge infrastructure would be maintained as in the past. The refuge would seek to improve access via the main refuge road and various trails. Efforts would be made to provide access to the northeast section of the refuge, and access via Cat Island Road would be pursued. The refuge would hire or assign staff to the refuge. Staff may include one or more of the following: A Refuge Manager, a Volunteer Coordinator, an Equipment Operator, a Law Enforcement Officer, a Forester, and a Biologist. Any or all of these may be shared positions among refuges in the Lower Mississippi River Refuge Complex.

*Alternative C: Full Resource Management With Enhanced Public Use*

Under this alternative, as with alternative B, the refuge's natural resources would be actively managed to enhance priority species habitats. A full inventory and monitoring program, including vegetation mapping and plant and wildlife surveys, would be instituted under a new Inventory and Monitoring Plan. Monitoring activities would be conducted by refuge staff, with the assistance of volunteers and partners. An aggressive approach would be taken to control invasive plants and animals, particularly feral hogs. Trapping and shooting by refuge staff and/or contractors would be systematically implemented with the goal of keeping populations at levels that do not pose a significant risk to refuge resources. Forests on the refuge would be assessed according to a stand-entry table, and appropriate silvicultural treatments would be applied to achieve the habitat conditions described by the Lower Mississippi Valley Joint Venture Forest Resource Conservation Working Group. Abandoned food plots along the main road would be evaluated for restoration to support nocturnal woodcock habitat. Refuge hydrology and aquatic habitats on the refuge would be fully assessed and feasible management actions to restore and enhance their ability to support a native recreational fishery and species of concern would be taken.

The refuge cultural resources would be protected as required by law and described under alternative B; however, increased public outreach and law enforcement presence would be expected to reduce risks of illegal disturbance of cultural artifacts. Funding for cultural resource surveys and catalog efforts would be sought, and cultural resources would be integrated into all refuge management activities, including forest management and public use programs. Historical information about the refuge lands would be compiled and displayed.

Public use under alternative C would be more strongly emphasized. While the refuge would continue to forge and develop partnerships, it would also develop independent capacity to manage public use. This capacity would include significant personnel resources focused on environmental education and interpretation, hunting and fishing, and promoting wildlife observation and photography. Dedicated law enforcement resources would be allocated to the refuge to focus on enhancing public safety and enforcing applicable laws and regulations. The refuge would, if feasible, maintain bank fishing areas adjacent to culverts along the main road and/or at the small pond.

Connections to educational institutions in the nearby Baton Rouge metropolitan area would be strengthened, and public outreach would emphasize the role of conservation in supporting urban quality of life. The refuge would investigate the possibility of hosting an annual public event.

The refuge infrastructure would be enhanced. Roads would be improved to reduce overall maintenance costs, particularly those that result from annual flooding. The refuge would evaluate the feasibility of building roadside boat launches for use during flooded conditions. The refuge would work with State of Louisiana and West Feliciana Parish to improve the access road to the refuge. New bridges would be constructed on roads and All-Terrain Vehicles/Utility Terrain Vehicle (ATV/UTV) trails where needed. ATV/UTV trails would be hardened where necessary and maintained annually. The refuge would evaluate the feasibility of upgrading the River Road ATV trail to support automobile traffic. The trail and boardwalk at the Big Cypress would be improved. Maintenance and infrastructure on the hiking trails would be improved. Abandoned camps along the Mississippi River would be removed, along with associated debris. The refuge would establish a presence in St. Francisville to house staff and serve as a focus for public outreach. The refuge would hire a core staff team to include a Refuge Manager, a Park Ranger/Volunteer Coordinator, a Law Enforcement Officer, a Forester or Biologist, and an Equipment Operator. One or more of these positions would be primarily assigned to Cat Island NWR, while others may be shared with other refuges in the complex. Full staffing level dedicated to the refuge is anticipated to be approximately 3–4 full-time equivalents under this alternative.

**Next Step**

After the comment period ends, we will analyze the comments and address them.

**Public Availability of Comments**

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Authority**

This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd *et seq.*).

Dated: October 27, 2014.

**Mike Oetker,**

*Acting Regional Director.*

**Editorial Note:** This document was received for publication by the Office of Federal Register on April 28, 2015.

[FR Doc. 2015–10298 Filed 4–30–15; 8:45 am]

**BILLING CODE 4310–55–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS–R8–ES–2015–N068; 81420–1113–0000–F3]**

### Extension of Pacific Gas and Electric Safe Harbor Agreement for Interior Dune Species Located in Antioch Dunes in Contra Costa County, CA

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

**ACTION:** Notice of availability; receipt of application.

**SUMMARY:** This notice advises the public that Pacific Gas and Electric (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for a 5-year extension of their existing Enhancement of Survival permit under the Endangered Species Act of 1973, as amended (Act). The Safe Harbor Agreement (Agreement) is between the Applicant and the Service for the federally endangered Lange's metalmark butterfly, Antioch Dunes evening primrose, and Contra Costa wallflower. No changes are proposed to the Agreement other than extending the Enhancement of Survival Permit and associated Agreement for an additional 5 years.

**DATES:** To ensure consideration, please send your written comments by June 1, 2015.

**ADDRESSES:** Send comments to Mr. Rick Kuyper, via U.S. mail at U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W–2605, Sacramento, CA 95825, or via facsimile to (916) 414–6713.

**FOR FURTHER INFORMATION CONTACT:** Mr. Rick Kuyper, Sacramento Fish and Wildlife Office (see **ADDRESSES**); telephone: (916) 414–6600.

**SUPPLEMENTARY INFORMATION:** This notice advises the public that Pacific Gas and Electric (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for a 5-year extension of their existing Enhancement of Survival permit under the Endangered Species Act of 1973, as amended (Act). The Safe Harbor Agreement (Agreement) is between the Applicant and the Service for the federally endangered Lange's metalmark butterfly (*Apodemia mormo langei*), Antioch Dunes evening primrose (*Oenothera deltoides* ssp. *howellii*), and Contra Costa wallflower (*Erysimum capitatum* var. *angustatum*) (collectively referred to as the Covered Species). No changes are proposed to the Agreement other than extending the Enhancement of Survival Permit and associated Agreement for an additional 5 years.

#### Availability of Documents

You may obtain a copy of the Agreement by contacting the individual named above. You may also make an appointment to view the document at the above address during normal business hours.

#### Background

Under a Safe Harbor Agreement, participating landowners voluntarily undertake management activities on their property to enhance, restore, or maintain habitat benefiting species listed under the Act (16 U.S.C. 1531 *et seq.*). Safe Harbor Agreements, and the subsequent enhancement of survival permits that are issued pursuant to section 10(a)(1)(A) of the Act, encourage private and other non-Federal property owners to implement conservation efforts for listed species by assuring property owners that they will not be subjected to increased property use restrictions as a result of their efforts to attract listed species to their property, or to increase the numbers or distribution of listed species already on their property. Application requirements and issuance criteria for enhancement of survival permits through Safe Harbor Agreements are found in 50 CFR 17.22(c) and 17.32(c). These permits allow any necessary future incidental take of covered species above the mutually agreed-upon baseline conditions for those species in accordance with the terms and conditions of the permits and accompanying agreements.

#### Existing Agreement

*Description*

The Agreement covers two 6-acre parcels (Enrolled Property) that are located along the south shore of the San Joaquin River in Contra Costa County, California. The two parcels are located adjacent to, and on either side of, the 14-acre Sardis Unit of the Antioch Dunes National Wildlife Refuge (Refuge). Two transmission towers are located on the Enrolled Property—one 115 kV tower on the west parcel and one 230 kV tower on the east parcel. The Applicant relies on graveled and dirt access roads to reach all of its facilities on the Enrolled Property. Each tower has an established work area that is utilized for maintenance and operation activities.

*Purpose*

The purpose of this Agreement is for the Service and the Applicant to collaborate and implement conservation measures for the Covered Species. The Applicant has restored and maintained suitable habitat within the Enrolled Property within the Antioch Dunes system, as specified in the Agreement. Restoration actions have primarily involved controlling invasive plant species. The Applicant has allowed the Service to conduct native plant restoration activities as specified in the Agreement. The restoration activities have resulted in an increase in host plants for the Lange's metalmark butterfly throughout the Enrolled Property, thus resulting in a net conservation benefit for this species. Additionally, the restoration activities have decreased threats to the Contra Costa wallflower and the Antioch Dunes evening primrose by reducing the amount of invasive, nonnative plants that outcompete the federally endangered plants. The Agreement also contains a monitoring component that provides information on the success of weed eradication and assists the Refuge in early detection of new invasive plant species. Results of these monitoring efforts are provided to the Service by the Applicant in annual reports.

*Proposed Extension of Existing Agreement*

No changes are proposed to the Agreement other than extending the Enhancement of Survival Permit and associated Agreement for an additional 5 years. The proposed extension of the Enhancement of Survival permit and Agreement would authorize the incidental taking of the Covered Species associated with the restoration, enhancement, and maintenance of suitable habitat for the Covered Species; routine activities associated with maintenance and operation of the two transmission towers; and the potential future return of the Enrolled Property to baseline conditions.

Consistent with the Service's Safe Harbor Policy (64 FR 32717), the Service would issue a 5-year extension of the Enhancement of Survival Permit to the Applicant. This permit will authorize the Applicant to take the Covered Species incidental to the implementation of the management activities specified in the Agreement, incidental to other lawful uses of the

property including normal, routine land management activities, and incidental to return to baseline conditions if desired. Although take of listed plant species is not prohibited under the Act, and therefore cannot be authorized under an enhancement of survival permit, plant species may be included on a permit in recognition of the net conservation benefit provided to them under a safe harbor agreement. An applicant would receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(c)(5) and 17.32(c)(5)) for all species included in the Enhancement of Survival permit. In addition to meeting other criteria, actions to be performed under an Enhancement of Survival permit must not jeopardize the existence of federally listed fish, wildlife, or plants.

**Public Review and Comments**

Individuals wishing to view the Agreement, including a map of the proposed permit area, should contact the office and personnel listed in the **ADDRESSES** section above.

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.

The Service will evaluate this permit application, associated documents, and comments submitted thereon to determine whether the permit application meets the requirements of section 10(a) of the Act and National Environmental Policy Act (NEPA) regulations. If the Service determines that the requirements are met, we will issue a 5-year extension for the enhancement of survival permit under section 10(a)(1)(A) of the Act to the Applicant for take of the Covered Species incidental to otherwise lawful activities in accordance with the terms of the Agreement. The Service will not make our final decision until after the end of the 30-day comment period and will fully consider all comments received during the comment period.

**Authority**

The Service provides this notice pursuant to section 10(c) of the Act and pursuant to implementing regulations for NEPA (40 CFR 1506.6).

**Jennifer M. Norris,**

*Field Supervisor, Sacramento Fish and Wildlife Office, Sacramento, California.*

[FR Doc. 2015–10299 Filed 4–30–15; 8:45 am]

BILLING CODE 4310–55–P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS–HQ–IA–2015–N082; FXIA16710900000–156–FF09A30000]**

### Endangered Species; Marine Mammals; Receipt of Applications for Permit

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

**ACTION:** Notice of receipt of applications for permit.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

**DATES:** We must receive comments or requests for documents on or before June 1, 2015. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by June 1, 2015.

**ADDRESSES:** Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281; or email *DMAFR@fws.gov.*

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

**SUPPLEMENTARY INFORMATION:**

**I. Public Comment Procedures**

*A. How do I request copies of applications or comment on submitted applications?*

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

*B. May I review comments submitted by others?*

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**II. Background**

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and

transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

**III. Permit Applications**

*A. Endangered Species*

Applicant: Tulsa Zoo Management, Inc., Tulsa, OK; PRT–54405B

The applicant requests a permit to export one captive-bred Diana monkey (*Cercopithecus diana*) for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 1-year period.

Applicant: Florida International University, North Miami, FL; PRT–64111B

The applicant requests a permit to import up to 150 skin, shell, or blood tissue samples from up to 50 green sea turtles (*Chelonia mydas*) and up to 150 skin, shell, or blood tissue samples from up to 50 green Loggerhead sea turtles (*Caretta caretta*) for the purpose scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Miami-Dade Zoological Park and Gardens, Miami, FL; PRT–59493B

The applicant requests a permit to export two female pink pigeons (*Nesoenas mayeri*) for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Adrian Cieslak, Wallace, SC; PRT–19311B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for Cuban Crocodile (*Crocodilus rhombifer*), Saltwater crocodile (*Crocodilus porosus*), broad-snouted caiman (*Caiman latirostris*), Chinese alligator (*Alligator sinensis*), and common caiman (*Caiman crocodilus*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Project Survival, Dunlap, CA; PRT–46280B

The applicant requests a permit to import one wild female jaguar (*Panthera onca*) for the purpose of enhancement of the survival of the species from Sorocaba Zoo, Sorocaba, Brazil.

Applicant: Project Survival, Dunlap, CA; PRT–63546B

The applicant requests a permit to import one wild margay (Leopardus wiedii) and one captive born and six wild ocelots (*Leopardus pardalis*) for the purpose of enhancement of the survival of the species from Chiriqui Feline Center, Buqaba District, Chiriq Province, Panama.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Jason Hagan, Hallettsville, TX; PRT–58572B

Applicant: Jeffrey Hayer, Greenfield, MA; PRT–63304B

Applicant: Terrance Lucht, Houston, TX; PRT–62687B

Applicant: Jeffery Dobbins, Mountain View, AR; PRT–63973B

*B. Endangered Marine Mammals and Marine Mammals*

Applicant: Robert Rockwell, American Museum of Natural History, New York, NY; PRT–03086A

The applicant requests renewal of their permit to import up to 1,000 biological samples annually from polar bears (*Ursus maritimus*) from Canada for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above application to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

**Brenda Tapia,**

*Program Analyst/Data Administrator,*

Branch of Permits, Division of Management Authority.

[FR Doc. 2015–10135 Filed 4–30–15; 8:45 am]

BILLING CODE 4310–55–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

## DEPARTMENT OF ENERGY

### Western Area Power Administration

**[LLWY920000.L51010000.ER0000–LVRWK09K1160; WYW177893; COC72929; UTU87238; N86732]**

### Notice of Availability of the Final Environmental Impact Statement for the TransWest Express 600-kV Direct Current Transmission Project in Wyoming, Colorado, Utah, and Nevada, and Proposed Land Use Plan Amendments

**AGENCY:** Bureau of Land Management, Interior; and Western Area Power Administration, DOE.

**ACTION:** Notice of availability.

**SUMMARY:** In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM), Bureau of Reclamation (BOR), Utah Reclamation Mitigation Conservation Commission (URMCC), Western Area Power Administration (Western) and the United States Forest Service (Forest Service) announce the availability of the TransWest Express Transmission Project Final Environmental Impact Statement (EIS) and proposed land use plan amendments. The Final EIS analyzes the potential environmental consequences of granting a right-of-way (ROW) to TransWest Express, LLC (TransWest) to construct and operate an extra-high voltage (EHV) direct current (DC) transmission system (proposed Project).

**DATES:** BLM planning regulations (43 CFR 1610.5–2) state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed RMP Amendment/Final EIS. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**.

**ADDRESSES:** Copies of the Final EIS have been sent to Federal, State, and local governments, public libraries in the area affected by the proposed Project, and to interested parties that previously requested a copy. The Final EIS and supporting documents will be available electronically on the following BLM Web site: *http://www.blm.gov/wy/st/en/info/NEPA/documents/hdd/*

*transwest.html*. Copies of the Final EIS are available for public inspection at the locations identified in the **SUPPLEMENTARY INFORMATION** section of this notice.

Protests on the BLM land use planning process must be in writing and mailed to one of the following addresses:

| Regular mail: | Overnight delivery: |
|---|---|
| BLM Director, (210) Attention: Protest Coordinator, P.O. Box 71383, Washington, DC 20024–1383. | BLM Director (210), Attention: Protest Coordinator, 20 M Street SE., Room 2134LM, Washington, DC 20003. |

**FOR FURTHER INFORMATION CONTACT:** Sharon Knowlton, Project Manager; Bureau of Land Management Wyoming State Office; P.O. Box 20678, Cheyenne, WY 82003; by telephone at 307–775–6124; or email to: *blm_wy_transwest_WYMail@blm.gov.* Persons who use a telecommunications device for the deaf 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.

For information about Western's involvement, contact Steve Blazek, Western NEPA Document Manager: Telephone 720–962–7265; email: *sblazek@wapa.gov;* address: Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213. For information about the Forest Service's involvement, contact Kenton Call, Forest Service Project Lead: Telephone 435–691–0768; email: *ckcall@fs.fed.us.* The Forest Service will provide a mailing address in its TransWest Project Final EIS NOA. For general information on the Department of Energy's NEPA review procedures or on the status of a NEPA review, contact Carol M. Borgstrom, Director of NEPA Policy and Compliance, GC–54, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; telephone 202–586–4600 or toll free at (800) 472–2756, or email: *askNEPA@hq.doe.gov.*

**SUPPLEMENTARY INFORMATION:** In November 2007, National Grid filed a ROW application with the BLM to construct and operate an EHV transmission line between Wyoming and delivery points in the Southwestern U.S. An amended application was filed on September 2, 2008, and project sponsorship was transferred to TransWest Express LLC (TransWest), a subsidiary of the Anschutz Corporation. TransWest submitted additional amended applications to the BLM in late 2008, 2010, 2011, 2012 and 2014 to reflect minor changes and refinements in the proposed Project.

In April 2010, the BLM and Western entered into a Memorandum of Understanding (MOU) in which the BLM and Western agreed to act as joint lead agencies for the EIS. The BLM's status as a joint lead agency is based on its potential Federal action to grant a ROW across BLM lands. Western's status as a joint lead agency is based on its potential Federal action to provide Federal funds for the proposed Project. Western and TransWest entered into a development agreement (executed in September 2011, amended in June 2014) wherein Western agreed to support Project development by providing technical assistance and/or financing.

The Forest Service is a cooperating agency in the proposed Project based on its potential Federal action to issue a special use permit across Forest Service lands. Additional cooperating agencies include Federal, State, tribal and local agencies. On January 4, 2011, the BLM and Western jointly published in the **Federal Register** (76 FR 379) a Notice of Intent to Prepare an EIS in compliance with Federal requirements FLPMA and NEPA. To allow the public an opportunity to review information associated with the proposed Project, the BLM held public meetings from January through March 2011 in Rawlins, Rock Springs, and Baggs, Wyoming; Craig, Rangely, and Grand Junction, Colorado; Castledale, Duchesne, Nephi, Delta, Richfield, Milford, Moab, Cedar City, St. George, Pine Valley, Central, and Enterprise, Utah; and Caliente, Overton, Henderson, and Las Vegas, Nevada. Issues and potential impacts to specific resources were identified during scoping and preparation of the Draft EIS. The following issues were identified in the scoping process:

- Selection of corridor alternatives;
- Potential private and public land use conflicts;
- Impacts and mitigation to fish, wildlife, vegetation, special status species and habitat;
- Public health and safety;
- Impacts to areas with Special Management designations;
- Cumulative impacts;
- Socioeconomic impacts; and
- Noxious weed control and reclamation.

The BLM and Western, in coordination with the Forest Service, other Federal, State, and local governments and agencies, considered all public scoping comments received as well as TransWest's refinements to identify the Agency Preferred Alternative. The Agency Preferred Alternative was developed through a comparative evaluation of routing opportunities and constraints and the relative potential impacts among the various alternative segments. The various alternative segments within regions were compared with each other in accordance with standard criteria. The primary criteria considered to select the Agency Preferred Alternative were:

(1) Maximize the use of designated utility corridors;

(2) Minimize requirements to amend agency land use plans;

(3) Avoid and minimize resource impacts regulated by law (for example, the Endangered Species Act);

(4) Avoid and minimize proximity to private residences and residential areas;

(5) Avoid and minimize resource impacts to reduce the magnitude and duration of adverse (residual) impacts;

(6) Minimize the use of private lands; and,

(7) Minimize transmission system construction, operation and maintenance expense.

The Environmental Protection Agency published a Draft EIS/Draft RMP Amendments NOA on July 3, 2013 in the **Federal Register** (78 FR 40163), which began a 90-day public comment period. To allow the public an opportunity to review and comment on the Draft EIS, the agencies held public meetings in July, August, and September 2013 in Rawlins and Baggs, Wyoming; Craig, Colorado; Vernal, Fort Duchesne, Duchesne, Price, Nephi, Delta, Cedar City, and St. George, Utah; Panaca and Henderson, Nevada. On December 6, 2013, the Forest Service published an additional NOA in the **Federal Register** (78 FR 73524) to initiate an additional 30-day public comment period specific to Forest Service decisions on the proposed Project. The agencies received over 1,800 comments, contained in 457 submissions, during the Draft EIS public comment periods. Principle comment issues included:

- Mitigation;

• Opposition to, or support for, specific routes;
• Effects to historic properties; and
• Effects to sensitive biological resources, including sage grouse.

Other comments provided specific edits and corrections to EIS sections and general support or opposition to the proposed Project. All submitted comments were addressed in the Final EIS. In response to public comments on the Draft EIS, the agencies developed a suite of hierarchical mitigation strategies for application to onsite, regional and compensatory mitigation, as applicable, as well as landscape level conservation and management actions to reduce resource impacts and achieve planning resource objectives for the planning areas crossed by the project. Specific examples include offsite compensatory mitigation for impacts to greater sage grouse and National Historic Trails. TransWest project proposal refinements include:

• Reduced separation distance from existing transmission to reflect updated Western Electricity Coordinating Council guidance;
• Removed or adjusted portions of the proposed Project that presented conflicts and/or did not address resource impacts not already addressed by the existing range of alternatives; and
• Reduced the width of the study area and refined the transmission alignment to reflect preliminary engineering designed to reduce resource impacts and conflicts.

As a result of cooperating agency input and public comments, refinements were made to the Agency Preferred Alternative presented in the Final EIS. The following discussions of proposed Project segments across various land ownerships and jurisdictions are specific to the Agency Preferred Alternative.

Approximately 276 miles (38 percent) of the Agency Preferred Alternative is located within designated Federal utility corridors. The Agency Preferred Alternative is co-located with existing transmission lines for a distance of 408 miles (56 percent) of the total length.

In Wyoming, the Agency Preferred Alternative crosses 59 miles of Federal, 4 miles of State, and 30 miles of private land. In Colorado, the Agency Preferred Alternative crosses 62 miles of Federal, 12 miles of State, and 15 miles of private land. In Utah, the Agency Preferred Alternative crosses 210 miles of Federal, 27 miles of State, and 153 miles of private land. In Nevada, the Agency Preferred Alternative crosses 137 miles of Federal, 14 miles of tribal, and 5 miles of private land. Lengths of the Agency Preferred Alternative by agency jurisdiction are found in the Final EIS, Chapter 2 Tables 2–23 through 2–26.

Other proposed Project alternatives cross additional Federal land jurisdictions that include: Colorado—BLM Grand Junction Field Office, and National Park Service; Utah—BLM Moab, Richfield, Price, and St. George Field Offices and National Forest System land with the Fishlake, Ashley, and Dixie National Forests; Nevada—National Park Service and the Department of Energy. These alternatives also cross State and private lands in addition to the Federal lands.

The requested ROW width would generally be 250 feet. The alternative segments were subdivided into four geographic regions to provide a better understanding of context for the impacts resulting from the proposed Project (Southern Wyoming and Northwestern Colorado; Northwestern Colorado, Eastern and Central Utah; Central and Southwestern Utah, Southern Nevada; Southern Nevada-Las Vegas metropolitan area). The approximately 728-mile Agency Preferred Alternative is discussed below, by region.

*Region I (Southern Wyoming, Northwestern Colorado).* The Agency Preferred Alternative transmission line route would extend approximately 157 miles from the vicinity of Sinclair, Carbon County, Wyoming to the vicinity of U.S. Highway 40 southwest of Maybell in western Moffat County, Colorado.

*Region II (Northwestern Colorado, Eastern Utah, Central Utah).* The Agency Preferred Alternative transmission line route would extend approximately 252 miles from Maybell Colorado, through eastern Utah, to the vicinity of the IPP near Delta, Millard County, Utah.

*Region III (Central Utah, Southwest Utah, Southern Nevada).* The Agency Preferred Alternative transmission line route would extend approximately 282 miles from the vicinity of the IPP, Millard County, Utah to the vicinity of Apex on Interstate 15, northeast of Las Vegas, Nevada.

*Region IV (Southern Nevada—Apex to the Marketplace Hub).* The Agency Preferred Alternative transmission line route would extend approximately 37 miles from Apex on Interstate 15 to the Marketplace Hub in the Eldorado Valley, southeast of Las Vegas.

The BLM, Western, and cooperating agencies worked together to develop routes that would conform to existing Federal land use plans. However, this objective was not reached for a number of the alternative routes analyzed in the Final EIS. Plan amendments that would be necessary to implement each of the evaluated alternatives were identified by affected agencies and analyzed in Chapter 4 of the Final EIS. The specific land use plan amendments that are actually needed will depend upon which route is selected in the agencies' final decisions. In the Final EIS, the BLM and Western identify the Agency Preferred Alternative, and BLM and Forest Service identify the requisite proposed plan amendments necessary to implement that alternative.

The proposed BLM plan amendments would: (1) Expand or extend an existing utility corridor that allows for overhead utilities; (2) Create a new utility corridor to allow for overhead utilities and exceptions to other resource stipulations if avoidance measures or impact mitigation are not feasible within the designated corridor; or (3) Create a one-time exception through a ROW exclusion area. Other BLM management plans could be amended depending upon the specifics of the route that is selected in the Record of Decision.

Copies of the Final EIS are available for public inspection during normal business hours at the following locations:

• BLM, Wyoming State Office, Public Reading Room, 5353 Yellowstone Road, Cheyenne, Wyoming 82009;
• BLM, Rawlins Field Office, 1300 North Third Street, Rawlins, Wyoming 82301;
• BLM, Colorado State Office, Public Reading Room, 2850 Youngfield Street, Lakewood, Colorado 80215–7093;
• BLM, Little Snake Field Office, 455 Emerson Street, Craig, Colorado 81625;
• BLM, White River Field Office, 220 East Market Street, Meeker, Colorado 81641;
• BLM, Grand Junction Office, 2815 H Road, Grand Junction, Colorado 81506;
• BLM, Utah State Office, Public Reading Room, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101–1345;
• BLM, Cedar City Field Office, 176 East DL Sargent Drive, Cedar City, Utah 84721;
• BLM, Fillmore Field Office, 95 East 500 North, Fillmore, Utah 84631;
• BLM, Moab Field Office, 92 East Dogwood, Moab, Utah 84532;
• BLM, Price Field Office, 125 South 600 West, Price, Utah 84501;
• BLM, Richfield Field Office, 150 East 900 North, Richfield, Utah 84701;
• BLM, St. George Field Office, 345 East Riverside Drive, St. George, Utah 84790;
• BLM, Vernal Field Office, 170 South 500 East, Vernal, Utah 84078;
• BLM, Nevada State Office, Public Reading Room, 1340 Financial Blvd., Reno, Nevada 89502;

• BLM, Caliente Field Office, U.S. Highway 93, Building #1, Caliente, Nevada 89008;

• BLM, Las Vegas Field Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130; and

• Forest Service (Lead Forest Office) Dixie National Forest, 1789 North Wedgewood Lane, Cedar City, Utah 84721.

A limited number of paper copies of the document will be available as supplies last. To request a copy, contact Sharon Knowlton, Project Manager, BLM Wyoming State Office, P.O. Box 20678, Cheyenne, WY 82003.

*BLM Land Use Plan Amendments and the Protest Process:* Depending on the route alternative, potential plan amendments proposed by the BLM are needed for the portions of the proposed Project crossing BLM-administered lands that do not conform to the respective land use plan. These include the following:

• Region I. Two plan amendments would be required. The BLM Rawlins and Little Snake Field Office plans would be affected.

• Region II. One to four plan amendments would be required. The BLM White River, Vernal, Price, and Salt Lake Field Office plans would be affected.

• Region III. One plan amendment would be required. The BLM Caliente Field Office plan would be affected.

• Region IV. No plan amendments would be required.

Instructions for filing a protest with the Director of the BLM regarding the proposed BLM land use plan amendments may be found in the ''Dear Reader'' Letter of the Final EIS and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the ''**ADDRESSES**'' section above. Emailed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular mail or overnight delivery postmarked by the close of the protest period. Under these conditions, the BLM will consider the email as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct emails to *protest@blm.gov.*

*Forest Service Land Use Plan Amendments:* The following land use plan amendments are proposed by the Forest Service for the portions of the proposed Project crossing National Forest Lands to conform to the respective Forest Service Plans:

• Region II. The Uinta, Ashley, Manti-LaSal, Fishlake, and Dixie National Forest plans would be affected by one or more of the alternatives.

Project-specific amendments for the Uinta and Manti La-Sal National Forest Plans are identified for the Agency Preferred Alternative.

*Agency Decisions on the proposed Project:* Based on the environmental analysis in this Final EIS, the BLM Wyoming State Director will decide whether to authorize, authorize with modifications, or deny the application based on the proposed Project, Agency Preferred Alternative, alternatives, or any combination thereof on Public Lands. Based on the BLM decision, the Administrator for Western will decide whether it would use its borrowing authority to partially finance and hold partial ownership with TransWest in the resulting transmission facilities and capacity. The Forest Service will issue a separate ROD specific to its decision whether to authorize a Special Use Permit on National Forest System land.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Mark A. Gabriel,**

*Administrator, Western Area Power Administration.*

**Mary Jo Rugwell,**

*Acting BLM Wyoming State Director.*

[FR Doc. 2015–10248 Filed 4–30–15; 4:15 pm]

BILLING CODE 4310–22–P

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

**[S1D1S SS08011000 SX066A000 67F 134S180110; S2D2S SS08011000 SX066A00 33F 13xs501520]**

### Notice of Availability of the Final Four Corners Power Plant and Navajo Mine Energy Project Environmental Impact Statement

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

**ACTION:** Notice of Availability.

**SUMMARY:** In accordance with the National Environmental Policy Act of 1969, *et seq.* (NEPA) the Office of Surface Mining Reclamation and Enforcement (OSMRE) has prepared a Final Environmental Impact Statement (FEIS) for the Four Corners Power Plant (FCPP) and Navajo Mine Energy Project, and is announcing its availability.

**DATES:** The OSMRE will not issue a final decision on the Proposed Action and Alternatives for a minimum of 30 days from the date that the U.S. Environmental Protection Agency (USEPA) publishes this notice in the **Federal Register**.

**ADDRESSES:** People interested in reviewing the FEIS can access the document via OSMRE's Web site at: *http://www.wrcc.osmre.gov/Current_Initiatives/FCNAVPRJ/FCPPEIS.shtm.* Copies of the FEIS are available to the public at the OSMRE's Western Region office, located at 1999 Broadway, Suite 3320, Denver, Colorado 80202–5733. Paper and CD copies of the FEIS are also available at the following locations:

Navajo Nation Library—Highway 264 Loop Road, Window Rock, AZ 86515

Navajo Nation Division of Natural Resources—Executive Office Building 1–2636, Window Rock Blvd., Window Rock, AZ 86515

Hopi Public Mobile Library—1 Main Street, Kykotsmovi, AZ 86039

Albuquerque Main Library—501 Copper Ave., NW., Albuquerque, NM 87102

Cortez Public Library—202 N. Park Street, Cortez, CO 81321

Durango Public Library—1900 E. Third Ave., Durango, CO 81301

Farmington Public Library—2101 Farmington Ave., Farmington, NM 87401

Octavia Fellin Public Library—115 W. Hill Ave., Gallup, NM 87301

Shiprock Branch Library—U.S. Highway 491, Shiprock, NM 87420

Tuba City Public Library—78 Main Street, Tuba City, AZ 86045

Chinle Chapter House—Highway 191, Chinle, AZ 86503

Coalmine Canyon Chapter House—Highway 160 and Main Street, Tuba City, AZ 86045

Nenahnezad Chapter House—County Road 6675, Navajo Route 365, Fruitland, NM 87416

Shiprock Chapter House—East on Highway 64, Shiprock, NM 87420

Tiis Tsoh Sikaad Chapter House—12 miles east of U.S. 491 on Navajo Route 5 and ½ mile south on Navajo Route 5080

Upper Fruitland Chapter House—N562 Building #006–001, North of Highway N36, Fruitland, NM 87416

BLM Rio Puerco Field Office—435 Montano Road, NE., Albuquerque, NM 87107

BIA Navajo Region—301 West Hill Street, Gallup, NM 87301

BIA Chinle Office—Navajo Route 7, Building 136–C, Chinle, AZ 86503
BIA Eastern Navajo Office—Highland Road Code Talker Street, Building 222, Crownpoint, NM 87313
BIA Fort Defiance Office—Bonita Drive, Building 251–3, Fort Defiance, AZ 86504
BIA Ramah Office—HC–61, Box 14, Ramah, NM 87321
BIA Shiprock Office—Nataani Nez Complex Building, Second Floor, Highway 491 South, Shiprock, NM 87420
BIA Southern Pueblos Office—1001 Indian School Road, NW., Albuquerque, NM 87104
BIA Southern Ute Office—383 Ute Road, Building 1, Ignacio, CO 81137
BIA Ute Mountain Ute Office—Phillip Coyote Sr. Memorial Hall, 440 Sunset Blvd., Towaoc, CO 81334
BIA Western Navajo Agency—East Highway 160 and Warrior Drive, Tuba City, AZ 86045

In addition, a limited number of CD copies of the FEIS have been prepared and are available upon request. Because of the time and expense in producing and mailing CD and paper copies, OSMRE requests that the public review the Internet or publicly available copies, if possible. You may obtain a CD by contacting the person identified in **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** For further information contact Mychal Yellowman, Project Coordinator, telephone: 303–293–5049; address: 1999 Broadway, Suite 3320, Denver, Colorado 80202–5733; email: *myellowman@osmre.gov.*

**SUPPLEMENTARY INFORMATION:**

I. Background on the Project
II. Background on the Four Corners Power Plant
III. Background on the Pinabete Mine Permit and the Navajo Mine Permit Renewal
IV. Alternatives
V. Response to Public Comment

## I. Background on the Project

The purpose of the Proposed Action is to allow continued operations of the FCPP and Navajo Mine and operation of the associated transmission lines. The Proposed Action would be consistent with federal Indian trust policies, including, but not limited to, a preference for tribal self-determination and promoting tribal economic development for all tribes affected by the Proposed Action. The FEIS evaluates the direct, indirect, and cumulative impacts of the Proposed Action at the FCPP, the proposed Pinabete Permit area, the existing Navajo Mine Permit area, and the rights-of-way renewals for segments of four transmission lines that transmit power from the FCPP. The public may view information about the Proposed Action on OSMRE's Web site at: *http://www.wrcc.osmre.gov/Current_Initiatives/FCNAVPRJ/FCPPEIS.shtm.*

Cooperating agencies for this NEPA process include: the Bureau of Indian Affairs (BIA), the Bureau of Land Management (BLM), the U.S. Environmental Protection Agency (USEPA), the U.S. Fish and Wildlife Service (USFWS), the National Park Service (NPS), the U.S. Army Corps of Engineers (USACE), the Navajo Nation, and the Hopi Tribe.

OSMRE complied with Section 106 of the National Historic Preservation Act (54 U.S.C. § 300101, *et seq.*) (NHPA Section 106) as provided for in 36 CFR 800.2(d)(3) concurrent with the NEPA process, including public involvement requirements and consultation with the State Historic Preservation Officer and Tribal Historic Preservation Officer. Consultation with Tribes and individual Native Americans were conducted in accordance with applicable laws, regulations, and Department of the Interior (DOI) trust policy as summarized in the FEIS. Consultation is complete and Programmatic Agreements have been signed by the consulting parties. These agreements are included as attachments to the FEIS.

OSMRE also conducted formal consultation with the USFWS pursuant to Section 7 of the Endangered Species Act (ESA; 16 U.S.C. 1536) and associated implementing regulations (50 CFR part 400). This formal consultation considered direct, indirect, and cumulative effects from the Proposed Action, and USFWS prepared a Biological Opinion which is included as an attachment to the FEIS.

Federal actions related to FCPP and Navajo Mine Energy Project will comply with all applicable laws and regulations, including: the Indian Business Site Leasing Act, 25 U.S.C. § 415; the General Right-of-Way Act of 1948, 25 U.S.C. §§ 323–328; the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. §§ 1201–1328; the Clean Water Act, 33 U.S.C. §§ 1251–1387; the Clean Air Act, 42 U.S.C. §§ 7401–7671q; the Native American Graves Protection and Repatriation Act, 25 U.S.C. §§ 3001–3013; and Executive Orders relating to Environmental Justice, Sacred Sites, and Government-to-Government Consultation.

## II. Background on Lease Amendment No. 3 at the Four Corners Power Plant

The FCPP is a coal-fired electric generating station located on Navajo tribal trust lands. FCPP currently includes two energy generation units producing approximately 1,500 megawatts, and provides power to more than 500,000 customers throughout the southwestern U.S. Nearly 80 percent of the employees at the plant are Native American. Arizona Public Service (APS) operates the FCPP and executed a lease amendment (Lease Amendment No. 3) with the Navajo Nation to extend the term of the FCPP lease for an additional 25 years, to 2041. Continued operation of the FCPP would require several federal actions, including:

- BIA approval of Lease Amendment No.3 for the FCPP, pursuant to 25 U.S.C. 415. If approved, the ash disposal area would be expanded within the existing FCPP lease area. There are no additional proposed changes to the FCPP, the switch yard, or any of the transmission lines and ancillary facilities, as part of the Proposed Action.
- BIA issuance of renewed rights-of-way, pursuant to 25 U.S.C. 323, for the continued operation of the FCPP, switchyard, and ancillary facilities; for a 500 kilovolt (kV) transmission line and two 345 kV transmission lines; and for ancillary transmission line facilities, including the Moenkopi Switchyard, an associated 12 kV line, and an access road (collectively the ''existing facilities''). These existing facilities are located on Navajo tribal trust lands, except for the 500 kV transmission line, which crosses both Navajo and Hopi tribal trust lands. The Proposed Action would continue operation and maintenance of these facilities. No upgrades to the existing facilities are part of the Proposed Action.
- BIA issuance of renewed rights-of-way to the Public Service of New Mexico (PNM) for the existing 345 kV transmission line. The transmission line will continue to be maintained and operated as part of the Proposed Action. No upgrades to this transmission line are planned as part of the Proposed Action.

In August 2012, the USEPA published its Federal Implementation Plan (FIP) for the Best Available Retrofit Technology (BART) at FCPP (40 CFR 49.5512). As a result, APS decommissioned Units 1, 2, and 3 at the FCPP in December 2013, and will install selective catalytic reduction equipment on Units 4 and 5 by 2018.

## III. Background on Pinabete Mine Permit and the Navajo Mine Permit Renewal

NTEC proposes to conduct surface coal mining operations within a new 5,659-acre permit area, called the Pinabete Permit area. This proposed permit area lies within the boundaries

of the existing Navajo Mine lease, which is located adjacent to the FCPP on Navajo tribal trust lands. Surface mining operations would occur on an approximately 2,744-acre portion of the proposed Pinabete Permit area, with a total disturbance footprint, including staging areas, of approximately 4,100 acres. The proposed Pinabete Permit area would, in conjunction with the mining of any reserves remaining within the existing Navajo Mine Permit area (Federal SMCRA Permit NM0003F), supply low-sulfur coal to the FCPP at a rate of approximately 5.8 million tons per year. Development of the Pinabete Permit area and associated coal reserves would use surface mining methods, and based on current projected customer needs, would supply coal to FCPP for up to 25 years beginning in 2016. The proposed Pinabete Permit area would include previously permitted but undeveloped coal reserves within Area IV North of the Navajo Mine Lease, and unpermitted and undeveloped coal reserves in a portion of Area IV South of the existing Navajo Mine Lease. Approval of the proposed Pinabete Permit would require several federal actions, including:

- OSMRE approval of the new SMCRA permit.
- BLM approval of a revised Mine Plan developed for the proposed maximum economic recovery of coal reserves.
- USACE approval of a Section 404 Individual Permit for impacts to waters of the United States from proposed mining activities.
- USEPA approval of a new source Section 402 National Pollutant Discharge Elimination System (NPDES) Industrial Permit associated with the mining and reclamation operations and coal preparation facilities.
- BIA approval of a proposed realignment for approximately 2.8 miles of BIA 3005/Navajo Road N–5082 (Burnham Road) in Area IV South to avoid proposed mining areas. This realignment would not be needed until 2022; however, the potential impacts of this realignment are analyzed in the FEIS.
- BIA approval or grant of permits or rights-of-way for access and haul roads, power supply for operations, and related facilities.

In addition, in 2014, OSMRE administratively delayed its decision on NTEC's renewal application for its existing Navajo Mine SMCRA Permit No. NM00003F. The EIS, therefore, also addresses alternatives and direct, indirect, and cumulative impacts of the 2014 renewal application action.

**IV. Alternatives**

Alternatives considered in the FEIS include three different mine plan configurations at Navajo Mine; implementing highwall or longwall mining techniques at the Navajo Mine; two different ash disposal facility configurations at FCPP; conversion of FCPP to a renewable energy plant; implementing carbon capture and storage at FCPP; and use of an off-site coal supply option for FCPP.

**V. Revisions to the Draft EIS**

In accordance with the CEQ's regulations for implementing NEPA and the DOI's NEPA regulations, OSMRE solicited public comments on the Draft EIS. OSMRE responses to comments are included in Appendix F of the FEIS. Comments on the Draft EIS received from the public were considered and incorporated as appropriate into the FEIS. Public comments resulted in the addition of clarifying text, but did not change any of the impact analyses or significance determinations.

In addition, the FEIS includes updates based on evolving regulatory guidance and completion of the Section 106 and Section 7 consultation processes.

**Authority:** 40 CFR 1506.6, 40 CFR 1506.10.

Dated: April 16, 2015 .

**Joseph G. Pizarchik,**

*Director, Office of Surface Mining Reclamation and Control.*

[FR Doc. 2015–10020 Filed 4–30–15; 8:45 am]

BILLING CODE 4310–05–P

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–913]**

## Certain Hemostatic Products and Components Thereof; Commission Determination Not To Review an Initial Determination Granting a Motion To Terminate the Investigation on the Basis of Settlement; Termination of the Investigation

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 51) issued by the presiding administrative law judge (''ALJ'') on April 2, 2015, granting complainants' motion to terminate the above-identified investigation on the basis of settlement.

**FOR FURTHER INFORMATION CONTACT:** Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on April 7, 2014, based on a complaint filed on February 28, 2014, and supplemented on March 19, 2014, on behalf of Baxter International Inc. of Deerfield, Illinois; Baxter Healthcare Corporation of Deerfield, Illinois; and Baxter Healthcare SA of Switzerland (collectively, ''Baxter''). 79 FR 19124 (Apr. 7, 2014). The complaint alleged violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the sale for importation, and sale within the United States after importation of certain hemostatic products and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,303,981; 8,512,729; 6,066,325; 8,357,378; and 8,603,511. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337. The Commission's notice of investigation named as respondents Johnson & Johnson (''J&J'') of Brunswick, New Jersey; Ethicon, Inc. (''Ethicon'') of Somerville, New Jersey; Ferrosan Medical Devices A/S (''Ferrosan'') of Denmark; and Packaging Coordinators, Inc. (''PCI'') of Philadelphia, Pennsylvania. 79 FR 19125. The Office of Unfair Import Investigations was named as a party to the investigation. *Id.* Subsequently, the investigation was terminated with respect to J&J and PCI. *See* Notice of Commission Determination Not to Review an Initial Determination Partially Terminating the Investigation Based on a Withdrawal of the Complaint (July 14, 2014).

On March 31, 2015, Baxter moved to terminate the investigation as to respondents Ethicon and Ferrosan based

upon a settlement agreement between them. The parties asserted that there are no other agreements, written or oral, express or implied between them concerning the subject matter of this investigation. The Commission's Investigative Attorney filed a response in support of the motion.

On April 2, 2015, the ALJ issued an ID (Order No. 51), granting the motion to terminate the investigation as to respondents Ethicon and Ferrosan. The ALJ found that the settlement agreement appears to resolve the dispute between the parties, and that granting the motion would not adversely affect the public interest factors. No petitions for review were filed.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 27, 2015.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2015–10198 Filed 4–30–15; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–1047 (Second Review)]**

## Ironing Tables and Certain Parts Thereof From China; Institution of a Five-Year Review

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (the Act) to determine whether revocation of the antidumping duty order on ironing tables and certain parts thereof from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is June 1, 2015. Comments on the adequacy of responses may be filed with the Commission by July 14, 2015.

**DATES:** *Effective Date:* May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

**SUPPLEMENTARY INFORMATION:**

*Background.*—On August 6, 2004, the Department of Commerce issued an antidumping duty order on imports of ironing tables and certain parts thereof from China (69 FR 47868). Following the first five-year reviews by Commerce and the Commission, effective June 28, 2010, Commerce issued a continuation of the antidumping duty order on imports of ironing tables and certain parts thereof from China (75 FR 36629). The Commission is now conducting a second review pursuant to section 751(c) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(c)) to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

*Definitions.*—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise*. In its original determination and full first five-year review, the Commission found one *Domestic Like Product* consisting of ironing tables and certain parts thereof, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination and full first five-year review determination, the Commission defined the *Domestic Industry* as U.S. producers of the *Domestic Like Product*.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

*Participation in the proceeding and public service list.*—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–332, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

*Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.*—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

*Certification.*—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

*Written submissions.*—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is June 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is July 14, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *http://edis.usitc.gov*. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

*Inability to provide requested information.*—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

*Information To Be Provided In Response to This Notice of Institution:* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry*.

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product*. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2009.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in number of tables and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year,

assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in number of tables and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in number of tables and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2009, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

**Authority:** This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: April 27, 2015.

**Jennifer D. Rohrbach,**

*Supervisory Attorney.*

[FR Doc. 2015–10105 Filed 4–30–15; 8:45 am]

**BILLING CODE 7020–02–P**

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## INTERNATIONAL TRADE COMMISSION

**[Investigation Nos. 731–TA–770–773 and 775 (Third Review)]**

## Stainless Steel Wire Rod From Italy, Japan, Korea, Spain, and Taiwan; Institution of Five-Year Reviews

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (the Act) to determine whether revocation of the antidumping duty orders on stainless steel wire rod from Italy, Japan, Korea, Spain, and Taiwan would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is June 1, 2015. Comments on the adequacy of responses may be filed with the Commission by July 14, 2015.

**DATES:** Effective Date: May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–334, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.* On September 15, 1998, the Department of Commerce issued antidumping duty orders on stainless steel wire rod from Italy, Japan, Korea, Spain, Sweden, and Taiwan (63 FR 49327). Following first five-year reviews by Commerce and the Commission, effective August 13, 2004, Commerce issued a continuation of the antidumping duty orders on imports of stainless steel wire rod from Italy, Japan, Korea, Spain, and Taiwan (69 FR 50167). Commerce revoked the antidumping duty order on imports of stainless steel wire rod from Sweden, effective April 23, 2007 (72 FR 25261, May 4, 2007). Following the second five-year reviews by Commerce and the Commission, effective June 17, 2010, Commerce issued a continuation of the antidumping duty orders on imports of stainless steel wire rod from Italy, Japan, Korea, Spain, and Taiwan (75 FR 34424). The Commission is now conducting third reviews pursuant to section 751(c) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(c)) to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

*Definitions.* The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Countries* in these reviews are Italy, Japan, Korea, Spain, and Taiwan.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original and full first and second five-year review determinations, the Commission found one *Domestic Like Product* consisting of all stainless steel wire rod corresponding to Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original and full first and second five-year review determinations, the Commission defined the *Domestic Industry* as consisting of all domestic producers of stainless steel wire rod.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

*Participation in the proceeding and public service list.* Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

*Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.* Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

*Certification.* Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

*Written submissions.* Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is June 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is July 14, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the

Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

*Inability to provide requested information.* Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

*Information To Be Provided In Response to this Notice of Institution:* If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2009.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise*

in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* after 2009, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (Optional) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

**Authority:** This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: April 27, 2015.

**Jennifer Rohrbach,**

*Supervisory Attorney.*

[FR Doc. 2015–10117 Filed 4–30–15; 8:45 am]

**BILLING CODE 7020–02–P**

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## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–149 (Fourth Review)]**

## Barium Chloride From China; Institution of a Five-Year Review

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (the Act) to determine whether revocation of the antidumping duty order on barium chloride from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is June 1, 2015. Comments on the adequacy of responses may be filed with the Commission by July 14, 2015.

**DATES:** *Effective Date:* May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

**SUPPLEMENTARY INFORMATION:**

*Background.*—On October 17, 1984, the Department of Commerce issued an antidumping duty order on imports of barium chloride from China (49 FR 40635). Following first five-year reviews by Commerce and the Commission, effective March 10, 1999, Commerce issued a continuation of the antidumping duty order on imports of barium chloride from China (64 FR 42654, August 5, 1999). Following second five-year reviews by Commerce and the Commission, effective August 5, 2004, Commerce issued a continuation of the antidumping duty order on imports of barium chloride from China (69 FR 47405). Following the third five-year reviews by Commerce and the Commission, effective June 28, 2010, Commerce issued a continuation of the antidumping duty order on imports of barium chloride from China (75 FR 36629). The Commission is now conducting a fourth review pursuant to section 751(c) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(c)) to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

*Definitions.*—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise*. In its original determination, the Commission defined the *Domestic Like Product* as crystalline and anhydrous barium chloride, excluding high purity barium chloride. In its expedited first and second five-year review determinations and its full third five-year review determination, the Commission found one *Domestic Like Product* coextensive with Commerce's scope: All forms of barium chloride, including crystalline,

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–333, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

anhydrous, and high purity. For purposes of responses to this notice, the *Domestic Like Product* is all forms of barium chloride, including crystalline, anhydrous, and high purity.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination, its expedited first and second five-year review determinations, and its full third five-year review determination, the Commission defined the *Domestic Industry* as all domestic producers of the *Domestic Like Product*.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

*Participation in the proceeding and public service list.*—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

*Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.*—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

*Certification.*—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

*Written submissions.*—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is June 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is July 14, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *http://edis.usitc.gov*. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

*Inability to provide requested information.*—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

*INFORMATION TO BE PROVIDED IN RESPONSE TO THIS NOTICE OF INSTITUTION:* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity

specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry*.

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2009.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country*.

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2009, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (Optional) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

**Authority:** This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: April 27, 2015.

**Jennifer Rohrbach,**

*Supervisory Attorney.*

[FR Doc. 2015–10108 Filed 4–30–15; 8:45 am]

BILLING CODE 7020–02–P

## INTERNATIONAL TRADE COMMISSION

**[Investigation Nos. 701–TA–464 and 731–TA–1160 (Review)]**

## Prestressed Concrete Steel Wire Strand From China; Institution of a Five-Year Review

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (the Act) to determine whether revocation of the antidumping and countervailing duty orders on prestressed concrete steel wire strand from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is June 1, 2015. Comments on the adequacy of responses may be filed with the Commission by July 14, 2015.

**DATES:** *Effective Date:* May 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.*—On June 29, 2010, the Department of Commerce issued an antidumping duty order on imports of prestressed concrete steel wire strand from China (75 FR 37382). On July 7, 2010, the Department of Commerce issued a countervailing duty order on imports of prestressed concrete steel wire strand from China (75 FR 38977). The Commission is conducting reviews pursuant to section 751(c) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(c)) to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

*Definitions.*—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Country* in these reviews is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined a single *Domestic Like Product* coextensive with Commerce's scope, that is, all types, grades, and diameters of prestressed concrete steel wire strand, whether uncoated (uncovered) or coated (covered), other than of stainless steel, which is suitable for use in, but not limited to, prestressed concrete (both pre-tensioned and post-tensioned) applications. Prestressed concrete steel wire strand made from galvanized wire is excluded from the scope if the zinc and/or zinc oxide coating meets or exceeds the 0.40 oz./ft.$^2$ standard set forth in ASTM–A–475.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the *Domestic Industry* to include all domestic producers of prestressed concrete steel wire strand.

(5) The *Order Date* is the date that the antidumping and countervailing duty orders under review became effective. In the review of the antidumping duty order, the *Order Date* is June 29, 2010. In the review of the countervailing duty order, the *Order Date* is July 7, 2010.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

*Participation in the proceeding and public service list.*—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

*Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.*—Pursuant to section 207.7(a) of the Commission's

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–331, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

*Certification.*—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

*Written submissions.*—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is June 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is July 14, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

*Inability to provide requested information.*—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

*Information To Be Provided in Response to This Notice of Institution:* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales,

internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

**Authority:** This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: April 27, 2015.

**Jennifer Rohrbach,**

*Supervisory Attorney.*

[FR Doc. 2015–10116 Filed 4–30–15; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

### Comment Request for Information Collection for ETA 9166, Pre-Implementation Planning Checklist Report for State Unemployment Insurance (UI) Information Technology (IT) Modernization Projects; New Collection

**AGENCY:** Employment and Training Administration (ETA), Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collection of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Building on lessons learned from previous state implementations of modernized UI IT systems, ETA commissioned the development of a UI IT Modernization Pre-Implementation Planning Checklist for states to use prior to ''going live'' with a new system. The checklist is expected to validate that all necessary system functions are available and/or that alternative workarounds are developed prior to the production launch of the UI IT system to help avoid major disruption of services to UI customers and to prevent delays in making UI benefit payments when due. In addition, the checklist will be used by ETA to identify the technical assistance needs of State Workforce Agencies (SWAs) in support of successful implementation of UI IT Modernization projects. This comprehensive checklist denotes critical functional areas that states should verify prior to launching including, but not limited to, technical IT functions and UI business processes that interface with the new system. The list of critical areas identified in the checklist includes, among others,

- Verification for essential UI Benefit and Tax functions,
- Interstate Connection (ICON) network and UI reporting interfaces,

- System Error handling,
- End-user support mechanisms,
- Alternate access options and usability issues,
- Policies and Procedures development and dissemination
- Technical preparation,
- Call Center and Customer Service operations,
- Staffing and Staff Training on new system operations,
- Help Desk support,
- Management oversight,
- Vendor support and
- Communications.

The new ETA 9166 will be used by the National and regional offices to ensure that states have plans to address critical issues prior to launching a new UI IT system and to identify areas where SWAs may need technical assistance to support successful implementation of UI IT Modernization projects. This information will include the project title and purpose, the project timeline and milestones, and a narrative description of the project implementation status. It will also include explanations of plans or workarounds to address the areas of potential issues identified in the implementation checklist, an explanation of any portion of the project that will experience delays in implementation, mitigation proposals for addressing problems and new project timelines (if applicable), a self-reported designation of the implementation status, and a discussion of identified technical assistance needs for the successful completion of the project.

ETA believes that the use of this checklist as a planning tool will help states ensure the availability of mission critical functions as the state prepares for the launch of a new system and following the launch of a new system.

Currently, ETA is soliciting comments concerning a new collection of information: ETA 9166, Unemployment Insurance (UI) Information Technology (IT) Modernization Pre-Implementation Planning Checklist Report.

**DATES:** Written comments must be submitted to the office listed in the addressee section below on or before June 30, 2015.

**ADDRESSES:** Send comments to Paul Bankes, U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Avenue NW., Frances Perkins Bldg. Room S–4524, Washington, DC 20210, telephone number (202) 693–3053 (this is not a toll-free number) or by email: *bankes.paul@dol.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The information to be reported on the ETA 9166 report will be used by the National and regional offices to validate that states are positioned to successfully ''go live'' with a new system and to provide any needed technical assistance as appropriate, in partnership with the Information Technology Support Center operated by the National Association of State Workforce Agencies, in support of successful implementation of UI IT Modernization projects. This information will include the UI IT Modernization project title (*e.g.* State project or Consortium name) and the associated Report on Pre-Implementation Planning Checklist results. For each sub-element identified in the checklist:

- Provide a brief report detailing the status of the project as it relates to addressing the particular sub-element issue(s);
- provide a self-reported designation of the implementation status;
- provide/attach explanations of any workarounds, if applicable, to be used in implementation;
- provide/attach explanations of any portions of the project that will experience delays in implementation;
- describe any mitigation proposals for addressing any problems;
- describe new project timelines, if applicable; and
- describe any discussion of identified technical assistance needs for the successful completion of the project or any sub-element of the project.

The collection will enable ETA to identify and provide appropriate technical assistance needs to a state on issues in the checklist and ensure states have plans for addressing critical issues prior to launching a new UI IT system.

## II. Review Focus

The Department is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary to describe the status of the SWA's new UI IT system activities, 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

## III. Current Actions

*Type of Review:* New collection.

*Title:* Unemployment Insurance (UI) Information Technology (IT) Modernization Pre-Implementation Planning Checklist Report, ETA 9166.

*OMB Number:* 1205—0NEW.

*Affected Public:* State Government.

*Estimated Total Annual Respondents:* 3–5.

*Annual Frequency:* One-time response.

*Estimated Total Annual Responses:* 3–5.

*Average Time per Response:* 120 hours.

*Estimated Total Burden Hours:* 360–600 hours per year.

*Total Burden Cost (Capital/Startup):* $0.

*Total Burden Cost (Reporting*):* $18,979–$31,620.

* We envision the report will be completed by some combination of an IT Project Manager and the state's UI Director. Based on budget allocations, a figure of $52.72 was derived for the average hourly wage of state agency UI Directors and IT staff for fiscal year 2015.

We will summarize and/or included in the request for OMB approval of the ICR, the comments received in response to this comment request; they will also become a matter of public record.

**Portia Wu,**

*Assistant Secretary for Employment and Training, Labor.*

[FR Doc. 2015–10161 Filed 4–30–15; 8:45 am]

BILLING CODE 4510–FW–P

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## DEPARTMENT OF LABOR

### Employment and Training Administration

### Workforce Investment Act of 1998 (WIA); Notice of Incentive Funding Availability Based on Program Year (PY) 2013 Performance

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor (DOL), in collaboration with the Department of Education (ED), announces that three States are eligible to apply for WIA (Public Law 105–220, 29 U.S.C. 2801 *et seq.*) incentive grant awards authorized by section 503 of the

WIA. The Workforce Innovation and Opportunity Act, signed into law on July 22, 2014, Public Law 113–128, eliminates incentive awards for state performance. PY 2013 is the last year that incentive grants will be awarded to states under WIA.

**DATES:** The three eligible States must submit their applications for incentive funding to the address listed below by June 15, 2015.

**ADDRESSES:** Submit applications to the Employment and Training Administration, Office of Policy Development and Research, Division of Strategic Planning and Performance, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210, *Attention:* Caterra Castile and Luke Murren. Telephone number: 202–693–3733 (this is not a toll-free number). Fax: 202–693–2766. Email: *castile.caterra@dol.gov* and *murren.luke@dol.gov.* Information may also be found at the ETA Performance Web site: *http://www.doleta.gov/performance.* Additional information on how to apply can be found in Training and Employment Guidance Letter 20–01 Change 13, which will be forthcoming.

**FOR FURTHER INFORMATION CONTACT:** Luke Murren at *Murren.Luke@dol.gov.*

**SUPPLEMENTARY INFORMATION:** Three States (see Appendix) qualify to receive a share of the $9 million available for incentive grant awards under WIA section 503. These funds, which were contributed by ED from appropriations for the Adult Education and Family Literacy Act at WIA title II (AEFLA), are available for the eligible States to use through June 30, 2017, to support innovative workforce development and education activities that are authorized under WIA title IB (Workforce Investment Systems) or WIA title II (AEFLA), or under the Carl D. Perkins Career and Technical Education Act of 2006 (Perkins IV), 20 U.S.C. 2301 *et seq.,* as amended by Public Law 109–270. In order to qualify for a grant award, a State must have exceeded its performance levels for WIA title IB and WIA title II. (Perkins IV removed the requirement that funds be reserved to carry out section 503 of WIA which only referenced Public Law 105–332 (Perkins III); thus, DOL and ED do not consider States' performance levels under Perkins IV in determining eligibility for incentive grants under section 503 of WIA). The performance related goals used to determine a State's eligibility status include: (1) Employment after training and related services, as well as retention in employment, and (2) improvements in literacy levels, among other measures. After review of the performance data submitted by States to DOL and ED, each Department determined which States exceeded their performance levels for its respective program(s) (the Appendix at the bottom of this notice lists the eligibility of each State by program). These lists were compared, and States that exceeded their performance levels for both programs are eligible to apply for and receive an incentive grant award.

The States eligible to apply for incentive grant awards and the amounts they are eligible to receive are listed in the following chart:

| State | Total award |
|---|---|
| Minnesota | $3,000,000 |
| North Dakota | 3,000,000 |
| Rhode Island | 3,000,000 |

**Portia Wu,**

*Assistant Secretary for Employment and Training, Labor.*

APPENDIX

| State | Incentive grants program year 2013 exceeded state performance levels | | |
|---|---|---|---|
| | WIA title IB | AEFLA (WIA title II—Adult education) | WIA title IB; AEFLA |
| Alabama | | | |
| Alaska | X | | |
| Arizona | | | |
| Arkansas | | | |
| California | | | |
| Colorado | X | | |
| Connecticut | | | |
| District of Columbia | | | |
| Delaware | | | |
| Florida | | | |
| Georgia | | X | |
| Hawaii | | | |
| Idaho | | X | |
| Illinois | | X | |
| Indiana | X | | |
| Iowa | | X | |
| Kansas | X | | |
| Kentucky | | | |
| Louisiana | | | |
| Maine | | | |
| Maryland | X | | |
| Massachusetts | | X | |
| Michigan | | | |
| **Minnesota** | X | X | X |
| Mississippi | | | |
| Missouri | | X | |
| Montana | | X | |
| Nebraska | X | | |
| Nevada | | | |
| New Hampshire | | X | |
| New Jersey | | | |
| New Mexico | | | |
| New York | | X | |

APPENDIX—Continued

| State | Incentive grants program year 2013 exceeded state performance levels | | |
|---|---|---|---|
| | WIA title IB | AEFLA (WIA title II—Adult education) | WIA title IB; AEFLA |
| North Carolina | | | |
| **North Dakota** | X | X | X |
| Ohio | X | | |
| Oklahoma | | | |
| Oregon | | | |
| Pennsylvania | | X | |
| Puerto Rico | | | |
| **Rhode Island** | X | X | X |
| South Carolina | X | | |
| South Dakota | | X | |
| Tennessee | X | | |
| Texas | | X | |
| Utah | X | | |
| Vermont | | | |
| Virginia | | | |
| Washington | | | |
| West Virginia | X | | |
| Wisconsin | | | |
| Wyoming | | | |
| Total | 14 | 15 | 3 |

* States in bold exceeded their performance levels for both WIA title IB and WIA title II programs.

[FR Doc. 2015–10223 Filed 4–30–15; 8:45 am]

BILLING CODE 4510–FN–P

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### Federal Council on the Arts and the Humanities; Arts and Artifacts Indemnity Panel Advisory Committee

**AGENCY:** National Endowment for the Humanities.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Federal Council on the Arts and the Humanities will hold two meetings of the Arts and Artifacts Indemnity Panel during May, 2015.

**DATES:** The meetings will be held on Thursday, May 21, 2015, from 2:00 p.m. to 5:00 p.m. and on Thursday, May 28, 2015 from 12:00 p.m. to 5:00 p.m.

**ADDRESSES:** The meetings will be held by teleconference originating at the National Endowment for the Arts, Washington, DC 20506.

**FOR FURTHER INFORMATION CONTACT:** Lisette Voyatzis, Committee Management Officer, 400 7th Street SW., Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov*. Hearing-impaired individuals who prefer to contact us by phone may use NEH's TDD terminal at (202) 606–8282.

**SUPPLEMENTARY INFORMATION:** The purpose of the meetings is for panel review, discussion, evaluation, and recommendation on applications for Certificates of Indemnity submitted to the Federal Council on the Arts and the Humanities, for exhibitions beginning on or after July 1, 2015. The meeting held May 21, 2015, will discuss applications for Certificates for domestic exhibitions and the meeting held May 28, 2015, will discuss applications for Certificates for international exhibitions. Because the meeting will consider proprietary financial and commercial data provided in confidence by indemnity applicants, and material that is likely to disclose trade secrets or other privileged or confidential information, and because it is important to keep the values of objects to be indemnified, and the methods of transportation and security measures confidential, I have determined that that the meeting will be closed to the public pursuant to subsection (c)(4) of section 552b of Title 5, United States Code. I have made this determination under the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated July 19, 1993.

Dated: April 27, 2015.

**Lisette Voyatzis,**

*Committee Management Officer.*

[FR Doc. 2015–10137 Filed 4–30–15; 8:45 am]

BILLING CODE 7536–01–P

## NATIONAL SCIENCE FOUNDATION

### Advisory Committee for Environmental Research and Education; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

*Name:* Advisory Committee for Environmental Research and Education.

*Dates:* June 19, 2015; 1:00 p.m.–2:30 p.m.

*Place:* Teleconference: (203) 607–6048 (participant code 6083852).

*Type of Meeting:* Open Teleconference.

*Contact Person:* Diane Pataki, National Science Foundation, Suite 655, 4201 Wilson Blvd., Arlington, Virginia 22230. Email: *dpataki@nsf.gov.*

*Minutes:* May be obtained from the contact person listed above.

*Purpose of Meeting:* To discuss finalization of draft Decadal Vision for Environmental Research and Education document the group is currently working on and how it will be rolled out.

**Agenda**

*Friday, June 19, 2015*

Discuss and refine draft of the Decadal Vision for Environmental Research and Education document.

Dated: April 28, 2015.

**Suzanne Plimpton,**

*Acting, Committee Management Officer.*

[FR Doc. 2015–10182 Filed 4–30–15; 8:45 am]

BILLING CODE 7555–01–P

## NUCLEAR REGULATORY COMMISSION

**[NRC–2015–0060]**

### Heat Release Rates of Electrical Enclosure Fires (HELEN-FIRE)

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft NUREG; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft NUREG, NUREG/CR–7197, ''Heat Release Rates of Electrical Enclosure Fires (HELEN-FIRE).''

**DATES:** Submit comments by June 15, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0060. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** David Stroup, Office of Nuclear Regulatory Research; telephone: 301–251–7609; email: *David.Stroup@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

**SUPPLEMENTARY INFORMATION:**

### I. Obtaining Information and Submitting Comments

*A. Obtaining Information*

Please refer to Docket ID NRC–2015–0060 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0060.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section. Draft NUREG/CR–7197, ''Heat Release Rates of Electrical Enclosure Fires (HELEN–FIRE)'' is available in ADAMS under Accession No. ML15075A495.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

*B. Submitting Comments*

Please include Docket ID NRC–2015–0060 in the subject line of your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publically disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include

identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

**II. Discussion**

Electrical enclosures are a potential source of fire in nuclear power plants because they contain both combustible materials and live electrical circuits. These fires have the potential to disrupt power, instrumentation, and control in the plant. Key parameters affecting fire in an electrical enclosure include its size, openings, electrical voltage, and combustible load. This report documents the results from 112 full-scale experiments conducted by the National Institute of Standards and Technology at the Chesapeake Bay Detachment of the Naval Research Laboratory to better quantify the heat release rate (HRR) and burning behavior of electrical enclosures. Eight electrical enclosures were acquired from Bellefonte Nuclear Generating Station, a plant owned by the Tennessee Valley Authority located in Hollywood, Alabama. The enclosures were originally low voltage control cabinets, but in the experiments they were reconfigured with various amounts and types of electrical cable to represent other kinds of enclosures that would be found in a typical plant. An oxygen consumption calorimeter was built on site to measure the HRR of the fire as a function of time. The peak HRR varied from 0.3 kW to 576 kW.

Dated at Rockville, Maryland, this 21st day of April 2015.

For the Nuclear Regulatory Commission.

**Mark Henry Salley,**

*Chief, Fire Research Branch, Division of Risk Analysis, Office of Nuclear Regulatory Research.*

[FR Doc. 2015–10128 Filed 4–30–15; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50–282, 50–306, and 72–10; NRC–2014–0236]**

## Northern States Power Company; Prairie Island Nuclear Generating Plant Independent Spent Fuel Storage Installation

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Exemption; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a May 16, 2013, request from Northern States Power Company (NSPM or the licensee), a Minnesota corporation doing business as Xcel Energy, for its specific license to operate an independent spent fuel storage installation (ISFSI) at the Prairie Island (PI) Nuclear Generating Plant. The licensee seeks relief from a regulatory provision with regard to the location of the primary alarm station.

**DATES:** Notice of issuance of exemption is given on May 1, 2015.

**ADDRESSES:** Please refer to Docket ID NRC–2014–0236 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0236. Address question about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's PDC:* 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:** Pamela Longmire, Ph.D., Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7000; email: *Pamela.Longmire@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The licensee possesses a specific license under part 72 of Title 10 of the *Code of Federal Regulations* (10 CFR) for the storage of spent fuel in an ISFSI at the PI Nuclear Generating Plant. Section 72.180, ''Physical protection plan,'' requires the licensee to comply with the physical protection requirements in 10 CFR 73.51, ''Requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste.'' The licensee is subject to the requirements of 10 CFR 73.51(d)(3), which specifies the location, components, and requirements for the primary alarm station for the ISFSI.

**II. Request/Action**

By letter dated May 16, 2013, NSPM submitted a request for an exemption from a specific portion of the requirements of 10 CFR 73.51(d), ''Physical protection systems, components, and procedures.'' Specifically, the licensee seeks relief from a regulatory provision of 10 CFR 73.51(d)(3) with regard to the location of the primary alarm station.

The NRC has the authority under 10 CFR 73.5 to grant a specific exemption from these requirements if the exemption is authorized by law and will not endanger life or property or the common defense and security, and the exemption is otherwise in the public interest.

**III. Discussion**

In accordance with the provisions of 10 CFR 73.21, physical protection plans for the storage of spent fuel and high-level radioactive waste are protected as Safeguards Information. This exemption request pertains to the location of the primary alarm station. The NRC evaluated the exemption request in greater detail in the safety evaluation report (SER). The SER is withheld from public disclosure in accordance with 10 CFR 2.390 because it contains security information.

*A. Regulatory Evaluation*

In the final rule, ''Physical Protection for Spent Nuclear Fuel and High-Level Radioactive Waste'' (63 FR 26955; May 15, 1998), the introductory text of 10 CFR 73.51(d) was revised to more clearly indicate the Commission's intent that alternative measures may also be acceptable for meeting the performance objectives of 10 CFR 73.51(d).

*B. Technical Evaluation*

Pursuant to 10 CFR 73.5, the Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in 10 CFR part 73 as it determines are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest. The NRC reviewed this request to determine whether the exemption should be granted. The NRC's evaluation of this exemption request is set forth in the SER.

The NRC has found that the NSPM meets the criteria for an exemption in 10 CFR 73.5. The NRC has determined that granting the exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or otherwise violate the Commission's regulations. Therefore, the exemption is authorized by law. This exemption would not reduce the safeguards effectiveness of the physical security plan, and would

allow NSPM to continue to maintain the 10 CFR 73.51 performance objectives of high assurance of public health and safety and the common defense and security. Therefore, granting the exemption would not endanger life or property or the common defense and security. Lastly, issuance of the exemption would facilitate effective security management at the PI site. Therefore, issuance of the exemption is in the public interest.

*C. Environmental Assessment*

The NRC also considered whether there would be any significant environmental impacts associated with the exemption. For this proposed action, the NRC performed an environmental assessment pursuant to 10 CFR 51.30. The proposed action is the approval of a request to exempt the applicant from certain requirements of 10 CFR 73.51(d)(3).

The environmental assessment concluded that the proposed action would not significantly impact the quality of the human environment. The NRC concludes that the proposed action would not result in any changes in the types or amounts of any radiological or non-radiological effluents that may be released offsite, and there would be no significant increase in occupational or public radiation exposure because of the proposed action. The environmental assessment and the finding of no significant impact were published in the **Federal Register** on October 24, 2014 (79 FR 63649).

## IV. Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 73.5, this exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants NSPM an exemption from certain requirements of 10 CFR 73.51(d)(3), as specified in the SER. The licensee did not request, and the Commission does not grant, relief from any other requirement in 10 CFR 73.51(d)(3) or any other provision.

Dated at Rockville, Maryland, this 23rd day of April 2015.

For the Nuclear Regulatory Commission.

**Anthony H. Hsia,**

*Deputy Director, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2015–10246 Filed 4–30–15; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 72–10; NRC–2013–0002]**

## Northern States Power Company; Prairie Island Independent Spent Fuel Storage Installation

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** License amendment application; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) reviewed an application by Northern States Power Company (NSPM) for amendment of Materials License No. SNM–2506 which authorizes NSPM to receive, possess, store, and transfer spent nuclear fuel and associated radioactive materials. The amendment sought to revise the cask cavity pressurization Technical Specifications for the spent fuel storage casks utilized at the Prairie Island (PI) Independent Spent Fuel Storage Installation (ISFSI).

**DATES:** Notice of amendment to Materials License No. SNM–2506 given on May 1, 2015.

**ADDRESSES:** Please refer to Docket ID NRC–2013–0002 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0002. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The Prairie Island License Amendment Request No. 9 package is available electronically under ADAMS Accession No. ML14143A202.
- *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:** Chris Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6877; email: *William.Allen@nrc.gov.*

**SUPPLEMENTARY INFORMATION:** By application dated May 23, 2014, as supplemented November 19, 2014, NSPM submitted to the NRC, in accordance with part 72 of Title 10 of the *Code of Federal Regulations* (CFR), a request to amend Special Nuclear Materials License No. SNM–2506 for its PI ISFSI site located in Welch, Minnesota. License No. SNM–2506 authorizes NSPM to receive, possess, store, and transfer spent nuclear fuel and associated radioactive materials resulting from the operation of the PI Power Plant in an ISFSI at the power plant site for a term of 20 years. Specifically, the amendment proposed to revise the cask cavity pressurization technical specifications for the spent fuel storage casks utilized at the PI ISFSI.

The NRC issued a letter dated July 30, 2014, notifying NSPM that the application was acceptable for review. In accordance with 10 CFR 72.16, a notice of docketing was published in the **Federal Register** on September 3, 2014 (79 FR 52375). The notice of docketing included an opportunity to request a hearing and to petition for leave to intervene. No requests for a hearing or petitions for leave to intervene were submitted.

The NRC prepared a safety evaluation report (SER) (ADAMS Accession No. ML15092A166) to document its review and evaluation of the amendment request. In addition, the NRC evaluated an assertion by PI that the amendment request satisfied the categorical exclusion criteria specified in 10 CFR 51.22(c)(11). Under 10 CFR 51.22(c)(11), a categorical exclusion is allowed for amendments to materials licenses which are administrative, organizational, or procedural in nature, or which result in a change to process operations or equipment, provided that (i) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, (ii) there is no significant increase in individual or cumulative occupational radiation exposure, (iii) there is no significant construction impact, and (iv) there is no significant increase in the potential for or consequences from radiological accidents. As explained in the SER, the NRC determined that the license

amendment satisfied the 10 CFR 51.22(c)(11) categorical exclusion criteria. Consequently, an environmental assessment and finding of no significant impact are not required.

Upon completing its review, the NRC staff determined the request complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), as well as the NRC's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment. The NRC approved and issued Amendment No. 9 to Special Nuclear Materials License No. SNM–2506, held by NSPM for the receipt, possession, transfer, and storage of spent fuel and associated radioactive materials at the PI ISFSI. Pursuant to 10 CFR 72.46(d), the NRC is providing notice of the action taken. Amendment No. 9 was effective as of the date of issuance, April 10, 2015.

Dated at Rockville, Maryland, this 10th day of April 2015.

For the Nuclear Regulatory Commission.

**Michele Sampson,**

*Chief, Spent Fuel Licensing Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2015–10247 Filed 4–30–15; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 72–1; NRC–2015–0113]**

## GE-Hitachi Nuclear Energy Americas, LLC; GE-Hitachi Morris Operation Independent Spent Fuel Storage Installation

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** License amendment application; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) reviewed an application by GE-Hitachi Nuclear Energy Americas, LLC, for an amendment of Special Nuclear Materials License No. SNM–2500, which authorizes GE-Hitachi Nuclear Energy Americas, LLC, to possess, store, and transfer spent nuclear fuel and associated radioactive materials at the GE-Hitachi Morris Operation's (GEMO) independent spent fuel storage installation (ISFSI). The requested amendment would change section 8.2.1 of the GEMO's technical specification to ensure that annual environmental reports are submitted in accordance with regulatory requirements. The application included adequate justification for the proposed changes. The NRC has docket, approved and issued the amendment.

**DATES:** May 1, 2015.

**ADDRESSES:** Please refer to Docket ID NRC–2015–0113 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0113. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; 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 obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The GE-Hitachi Morris Operation License Amendment Request No. 14 package is available electronically under ADAMS Accession No. ML15106A008.
- *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:** Pamela Longmire, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7000; email: *Pamela.Longmire@nrc.gov.*

**SUPPLEMENTARY INFORMATION:** On December 21, 2004, the NRC renewed Special Nuclear Materials License No. SNM–2500 for the GEMO ISFSI (ADAMS Accession No. ML043630433), located near Morris, Illinois. The renewed license authorizes GE-Hitachi Nuclear Energy Americas, LLC to possess, store, and transfer spent nuclear fuel and associated radioactive materials at the GEMO–ISFSI for a term of 20 years. The NRC also issued an environmental assessment and finding of no significant impact related to the issuance of the renewed ISFSI license on November 30, 2004 (ADAMS Accession No. ML043360409), in accordance with the National Environmental Policy Act, and in conformance with the applicable requirements of Title 10 of the Code of Federal Regulations (10 CFR part 51).

On June 25, 2013, GE-Hitachi Nuclear Energy Americas, LLC submitted to the NRC a request for a license amendment in accordance with § 72.56, ''Application for amendment of license.'' The requested amendment would change section 8.2.1 of the GEMO technical specification to ensure that annual environmental reports are submitted in accordance with regulatory requirements. The application included adequate justification for the proposed changes.

Pursuant to 10 CFR 72.46, the NRC has docketed, approved and issued Amendment No. 14 to Special Nuclear Materials License No. SNM–2500, held by GE-Hitachi Nuclear Energy Americas, LLC, for the possession, transfer and storage of spent fuel at the GEMO ISFSI. Amendment No. 14 is effective as of the date of issuance.

Amendment No. 14 complies with the standards and requirements of the Atomic Energy Act of 1954, as amended, and the Commission's rules and regulations. The Commission has made appropriate findings, as required by the Act and the Commission's rules and regulations in 10 CFR Chapter 1, which are set forth in Amendment No. 14. The issuance of Amendment No. 14 satisfied the criteria specified in 10 CFR 51.22(c)(11) for a categorical exclusion. Therefore, the preparation of an environmental assessment or an environmental impact statement is not required.

In accordance with 10 CFR 72.46(b)(2), the NRC has determined that Amendment No. 14 does not present a genuine issue as to whether public health and safety will be significantly affected. Therefore, the publication of a notice of proposed action and an opportunity for hearing or a notice of hearing is not warranted. Notice is hereby given of the right of interested persons to request a hearing on whether the action should be rescinded or modified.

Dated at Rockville, Maryland, this 16th day of April 2015.

For the Nuclear Regulatory Commission.

**Michele Sampson,**

*Chief, Spent Fuel Licensing Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2015–10245 Filed 4–30–15; 8:45 am]

BILLING CODE 7590–01–P

## OVERSEAS PRIVATE INVESTMENT CORPORATION

**[OMB–3420–0018]**

### Submission for OMB Review; Comments Request

**AGENCY:** Overseas Private Investment Corporation (OPIC).

**ACTION:** Notice and request for comments.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is modifying and renewing an existing previously approved information collection for OMB review and approval and requests public review and comment on the submission. Comments are being solicited on the need for the information; the accuracy of OPIC's burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

**DATES:** Comments must be received within sixty (60) calendar days of publication of this Notice.

**ADDRESSES:** Mail all comments and requests for copies of the subject form to OPIC's Agency Submitting Officer: James Bobbitt, Overseas Private Investment Corporation, 1100 New York Avenue NW., Washington, DC 20527. See **SUPPLEMENTARY INFORMATION** for other information about filing.

**FOR FURTHER INFORMATION CONTACT:** OPIC Agency Submitting Officer: James Bobbitt, (202) 336–8558.

**SUPPLEMENTARY INFORMATION:** All mailed comments and requests for copies of the subject form should include form number OPIC–129 on both the envelope and in the subject line of the letter. Electronic comments and requests for copies of the subject form may be sent to *James.Bobbitt@opic.gov,* subject line OPIC–129.

#### Summary Form Under Review

*Type of Request:* Revision of currently approved information collection.

*Title:* Sponsor Disclosure Report.

*Form Number:* OPIC–129.

*Frequency of Use:* One per investor per project.

*Type of Respondents:* Business or other institution (except farms); individuals.

*Standard Industrial Classification Codes:* All.

*Description of Affected Public:* U.S. companies or citizens investing overseas.

*Reporting Hours:* 1890 (3 hours per response).

*Number of Responses:* 630 per year.

*Federal Cost:* $64,801.80 ($51.43 × 630 × 2)

*Authority for Information Collection:* Sections 231, 234(a), 239(d), and 240A of the Foreign Assistance Act of 1961, as amended.

*Abstract (Needs and Uses):* The information provided in the OPIC–129 is used by OPIC as a part of the Character Risk Due Diligence/background check procedure (similar to a commercial bank's Know Your Customer procedure) that it performs on each party that has a significant relationship (10% or more beneficial ownership, provision of significant credit support, significant managerial relationship) to the projects that OPIC finances. The only change being made is to adjust the threshold from 5% to 10% in order to make OPIC's due diligence process more efficient and less resource intensive without significantly increasing the reputational and project risks associated with OPIC transactions.

Dated: February 23, 2015.

**Nichole Cadiente,**

*Administrative Counsel, Department of Legal Affairs.*

[FR Doc. 2015–10230 Filed 4–30–15; 8:45 am]

BILLING CODE 3210–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–74813; File No. SR–ODD–2015–01]**

### Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Approval of Accelerated Delivery of Supplement to the Options Disclosure Document Reflecting the Inclusion of Disclosure Regarding Foreign Currency Index Options and Changes to Disclosure Regarding Implied Volatility Index Options

April 27, 2015.

On May 20, 2014, the Options Clearing Corporation (''OCC'') submitted to the Securities and Exchange Commission (''Commission''), pursuant to Rule 9b–1 under the Securities Exchange Act of 1934 (''Act''),[1] five preliminary copies of a supplement to amend the options disclosure document (''ODD'') to include disclosure regarding foreign currency index options and amend disclosure regarding implied volatility index options (''April 2015 Supplement'').[2] On April 15, 2015, the Commission received from the OCC five definitive copies of the April 2015 Supplement.[3]

#### Foreign Currency Index Options

Currently, the ODD states that indexes that may underlie options include stock indexes, variability indexes, strategy-based indexes, dividend indexes, and relative performance indexes. In April 2013, the Commission approved a proposed rule change by the International Securities Exchange, LLC (''ISE'') to list options on the Dow Jones FXCM Dollar Index.[4] The April 2015 Supplement amends disclosures in the ODD to add foreign currency indexes as a type of index that can underlie an option, in order to accommodate the trading of options on the Dow Jones FXCM Dollar Index and similarly structured foreign currency indexes.[5] Specifically, the April 2015 Supplement adds new disclosure regarding the characteristics of foreign currency index options and their special risks. In addition, the supplement adds an example of the calculation of a foreign currency index. The supplement also amends disclosures in the ODD to accommodate the fact that components of foreign currency indexes are foreign currencies rather than securities (*e.g.,* by referring to ''components'' of an index rather than ''constituent securities'' of an index).

#### Implied Volatility Index Options

The ODD currently contains general disclosures on the characteristics and risks of trading standardized options on variability indexes. The ODD states that variability indexes are indexes intended

[1] 17 CFR 240.9b–1.

[2] *See* email from Jean M. Cawley, SVP and Deputy General Counsel, OCC, to Sharon Lawson, David Michehl, and Yue Ding, Division of Trading and Markets (''Division''), Commission, dated May 20, 2014.

[3] *See* letter from Jean M. Cawley, Senior Vice President and Deputy General Counsel, OCC, to Sharon Lawson, Senior Special Counsel, Division, Commission, dated April 14, 2015. The April 2015 Supplement also makes certain technical, non-substantive amendments to the ODD.

[4] *See* Securities Exchange Act Release No. 69365 (April 11, 2013), 78 FR 23321 (April 18, 2013) (SR–ISE–2013–14).

[5] The April 2015 Supplement is intended to accommodate the trading of options on foreign currency indexes that reflect the value of one currency, often the U.S. dollar, against a basket of foreign currencies. Foreign currency indexes are calculated using exchange rates.

to measure the implied volatility, or the realized variance or volatility, of specified stock indexes or specified securities. In January 2014, the Commission approved a proposed rule change by the ISE to list options on the Nations VolDex Index.[6] The April 2015 Supplement amends disclosures in the ODD regarding implied volatility index options to accommodate the listing of options on the Nations VolDex Index and similarly structured implied volatility indexes.[7] Specifically, the April 2015 Supplement amends the discussion of implied volatility index options by including disclosure regarding exercise settlement value calculations that use the mid-point of the bid and offer of the index components and the risks of the different calculation methodologies. The supplement also provides disclosure regarding the types of options that can be used to calculate implied volatility indexes (*i.e.,* out-of-the-money option series and hypothetical at-the-money option series; options with certain expiration months or weeks; number of days the options have until expiration).

The April 2015 Supplement is intended to be read in conjunction with the more general ODD, which discusses the characteristics and risks of options generally.[8]

Rule 9b–1(b)(2)(i) under the Act[9] provides that an options market must file five copies of an amendment or supplement to the ODD with the Commission at least 30 days prior to the date definitive copies are furnished to customers, unless the Commission determines otherwise, having due regard to the adequacy of the information disclosed and the public interest and protection of investors.[10] In addition, five copies of the definitive ODD, as amended or supplemented, must be filed with the Commission not later than the date the amendment or supplement, or the amended ODD, is furnished to customers. The Commission has reviewed the April 2015 Supplement, and the amendments to the ODD contained therein, and finds that, having due regard to the adequacy of the information disclosed and the public interest and protection of investors, the supplement may be furnished to customers as of the date of this order.

*It is therefore ordered,* pursuant to Rule 9b–1 under the Act,[11] that definitive copies of the April 2015 Supplement to the ODD (SR–ODD–2015–01), reflecting the inclusion of disclosure regarding foreign currency index options and changes to disclosure regarding implied volatility index options, may be furnished to customers as of the date of this order.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015–10136 Filed 4–30–15; 8:45 am]

**BILLING CODE 8011–01–P**

[6] *See* Securities Exchange Act Release No. 71365 (January 22, 2014), 79 FR 4512 (January 28, 2014) (SR–ISE–2013–42).

[7] The exercise settlement value for the Nations VolDex Index is calculated using the mid-point of the NBBO for the component options of the index, whereas most other index settlement values are calculated using transaction prices of the index components.

[8] The Commission notes that the options markets must continue to ensure that the ODD is in compliance with the requirements of Rule 9b–1(b)(2)(i) under the Act, 17 CFR 240.9b–1(b)(2)(i), including when changes regarding foreign currency index options and implied volatility index options are made in the future. Any future changes to the rules of the options markets concerning foreign currency index options and implied volatility index options would need to be submitted to the Commission under Section 19(b) of the Act. 15 U.S.C. 78s(b).

[9] 17 CFR 240.9b–1(b)(2)(i).

[10] This provision permits the Commission to shorten or lengthen the period of time which must elapse before definitive copies may be furnished to customers.

[11] 17 CFR 240.9b–1.

[12] 17 CFR 200.30–3(a)(39).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–74814; File No. SR–NYSEArca–2014–107]**

## Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment Nos. 2 and 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3, To Reflect Changes to the Means of Achieving the Investment Objective Applicable to the Guggenheim Enhanced Short Duration ETF

April 27, 2015.

### I. Introduction

On October 21, 2014, NYSE Arca, Inc. (''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 reflect certain changes to the description of the Guggenheim Enhanced Short Duration ETF (''Fund''), a series of Claymore Exchange-Traded Fund Trust (''Trust'').[3] On October 29, 2014, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1 thereto, was published for comment in the **Federal Register** on November 7, 2014.[4] The Commission received one comment on the proposal.[5] On December 10, 2014, the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On February 3, 2015, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change.[7] On March 16, 2015, the Exchange filed Amendment No. 2 to the proposed rule change,[8] and on March 24, 2015, the Exchange filed Amendment No. 3 to the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission previously approved the listing and trading of the shares (''Shares'') of the Fund. *See* Securities Exchange Act Release No. 64550 (May 26, 2011), 76 FR 32005 (Jun. 2, 2011) (SR–NYSEArca–2011–11) (''Prior Order''). *See also* Securities Exchange Act Release No. 64224 (Apr. 7, 2011), 76 FR 20401 (Apr. 12, 2011) (SR–NYSEArca–2011–11) (''Prior Notice,'' and together with the Prior Order, collectively ''Prior Release''). The Exchange represents that the Shares are currently listed and trading on the Exchange under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares.

[4] *See* Securities Exchange Act Release No. 73512 (Nov. 3, 2014), 79 FR 66442 (''Notice''). In Amendment No. 1 to the proposed rule change, the Exchange clarified that asset-backed securities in which the Fund may invest include collateralized debt obligations, as described in the Prior Release.

[5] Comments on the proposed rule change, including Amendment Nos. 2 and 3, can be found on the Commission's Web site, *available at http://www.sec.gov/comments/sr-nysearca-2014-107/nysearca2014107.shtml.*

[6] *See* Securities Exchange Act Release No. 73810, 79 FR 74783 (Dec. 16, 2014). The Commission determined that it was appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission designated February 5, 2015 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[7] *See* Securities Exchange Act Release No. 74199, 80 FR 7050 (Feb. 9, 2015) (''Order Instituting Proceedings''). In the Order Instituting Proceedings, the Commission noted, among other things, that questions remain as to whether the Exchange's proposal is consistent with the requirements of Section (6)(b)(5) of the Act, 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, and to protect investors and the public interest and asked questions regarding the liquidity and transparency of the Fund's proposed holdings in asset-backed securities.

[8] In Amendment No. 2, the Exchange: (1) Modified the proposal to permit the Fund to invest up to 20% of its assets in MBS and ABS that are privately issued, non-agency, and non-government sponsored entity, collectively defined as ''Private MBS/ABS'' and (2) made conforming changes in the proposal to reflect the defined term ''Private MBS/ABS.''

proposed rule change.[9] The Commission is publishing this notice to solicit comments on Amendments Nos. 2 and 3 from interested persons, and is approving the proposed rule change, as modified by Amendment Nos. 1, 2, and 3, on an accelerated basis.

## II. The Exchange's Description of the Proposal

The Exchange proposes to reflect certain changes to the measures that Guggenheim Funds Investment Advisors, LLC (''Adviser'') may use to implement the Fund's investment objective, which is to seek maximum current income, consistent with preservation of capital and daily liquidity.[10]

First, the Prior Release stated that the Fund may invest up to 10% of its assets in mortgage-backed securities (''MBS'') or in other asset-backed securities (''ABS'').[11] The Exchange proposes to modify this limitation to permit the Fund to invest up to 20% of its assets in MBS and ABS that are privately-issued, non-agency, and non-government sponsored entity (''Private MBS/ABS''). The Exchange notes that the holdings in Private MBS/ABS would be subject to the respective limitations on the Fund's investments in illiquid assets and high yield securities, as described below. According to the Exchange, this change to the Fund's investment limitations would allow the Adviser to better achieve the Fund's investment objective to seek maximum current income, consistent with preservation of capital and daily liquidity. In addition, the Exchange represents that the Fund's increased investment in Private MBS/ABS will continue to adhere to the Fund's investment strategy of investing in short duration, fixed income securities. The Exchange further notes that, because the Fund may invest no more than 10% of its net assets in high yield securities, the preponderance of the Fund's investments in Private MBS/ABS will be in investment grade instruments. Due to the quality of Private MBS/ABS in which the Fund will invest, the Exchange states that the Fund's additional investments in Private MBS/ABS should not expose the Fund to additional liquidity risk.

Second, the Prior Release stated that the Fund may invest up to an aggregate amount of 15% of its net assets in: (1) Illiquid securities; and (2) Rule 144A securities. The Exchange proposes to modify this limitation and permit the Fund to hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment),[12] including Rule 144A securities deemed illiquid by the Adviser, consistent with Commission guidance. According to the Exchange, the Adviser and the Trust's Board of Trustees will continue to evaluate each Rule 144A security based on the Fund's valuation procedures to oversee liquidity and valuation concerns. With respect to investment in illiquid assets, if changes in the values of the Fund's assets cause the Fund's holdings of illiquid assets to exceed the 15% limitation (as if liquid assets have become illiquid), the Fund will take such actions as it deems appropriate and practicable to attempt to reduce its holdings of illiquid assets.

Third, the Prior Release stated that the Fund primarily will invest in U.S. dollar-denominated, investment grade debt securities rated Baa or higher by Moody's Investors Service, Inc. (''Moody's''), or equivalently rated by Standard & Poor's Rating Group (''S&P'') or Fitch Investor Services (''Fitch''), or, if unrated, determined by the Adviser to be of comparable quality. The Exchange proposes to modify this representation, as described above, to a representation that the Fund primarily will invest in U.S. dollar-denominated, investment grade debt securities rated Baa3 or higher by Moody's,[13] or equivalently rated by S&P, Fitch, or by any other nationally recognized statistical rating organizations, or, if unrated, determined by the Adviser to be of comparable quality.

Fourth, the Prior Release stated that the Fund will invest at least 80% of its net assets in fixed income securities. The Fund proposes to modify this statement to permit the Fund to invest at least 80% of its net assets in fixed income securities and in exchange-traded funds (''ETFs'') and closed-end funds that invest substantially all of their assets in fixed income securities.[14] The Exchange represents that the shares of these ETFs and closed-end funds will be listed on a U.S. national securities exchange.

The Exchange represents that there is no change to the Fund's investment objective, and that the Fund will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.600. In addition, the Exchange represents that, except for the changes noted above, all other facts presented and representations made in the Prior Release remain unchanged.[15]

Additional information regarding the Trust, Fund, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, trading halts, dissemination and availability of information, distributions, and taxes can be found in the Prior Release, Notice, as modified by Amendment Nos. 1, 2, and 3, and the registration statement, as applicable.[16]

## III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act[17] and the rules and

[9] In Amendment No. 3, the Exchange made additional conforming changes in the proposal to reflect the defined term ''Private MBS/ABS,'' the preponderance of which will be investment grade.

[10] According to the Prior Release, the Fund uses a low duration strategy to seek to outperform the 1–3 month Treasury Bill Index, in addition to providing returns in excess of those available in U.S. Treasury bills, government repurchase agreements, and money market funds, while providing preservation of capital and daily liquidity. The Prior Release also stated that the Fund would hold, under normal circumstances, a diversified portfolio of fixed income instruments of varying maturities, but that have an average duration of less than one year.

[11] As stated in the Prior Release, this 10% limitation does not apply to securities issued or guaranteed by federal agencies or U.S. government sponsored instrumentalities, such as the Government National Mortgage Administration, the Federal Housing Administration, the Federal National Mortgage Association, and the Federal Home Loan Mortgage Corporation.

[12] In reaching liquidity decisions, the Adviser may consider the following factors: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

[13] According to the Exchange, ''Baa3'' is the lowest tier within the ''Baa'' rating.

[14] According to the Exchange, ETFs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); and Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600). The Fund will invest in the securities of ETFs registered under the Investment Company Act of 1940 (''1940 Act'') consistent with the requirements of Section 12(d)(1) of the 1940 Act, or any rule, regulation or order of the Commission or interpretation thereof.

[15] The Prior Release also stated that the Fund is considered non-diversified under the 1940 Act and can invest a greater portion of assets in securities of individual issuers than a diversified fund. According to the Exchange, Trust changed this representation in an amendment to the Trust's registration statement to state that the Fund is considered a diversified fund. To reflect this change in the registration statement, the Exchange's current proposed rule change states that the Fund is considered a diversified fund.

[16] *See supra* notes 3 and 4; *see also* Notice, *supra* note 4, at 66443 n.6 (referring to the registration statement on Form N–1A relating to the Fund (File Nos. 333–134551 and 811–21906)).

[17] 15 U.S.C. 78f.

regulations thereunder applicable to a national securities exchange.[18] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that the changes proposed by the Exchange with respect to the Fund are consistent with the listing standards applicable to other existing ETFs. Specifically, the Commission notes that, with respect to proposals to list and trade other Managed Fund Shares on the Exchange, it has previously approved similar limitations on MBS and ABS holdings and on illiquid assets.[20] The Commission also notes that it has previously approved the listing and trading of other series of Managed Fund Shares based on portfolios comprising fixed income securities of any credit rating, including investment grade securities rated Baa3 or higher,[21] and shares of other ETFs and exchange-traded closed-end funds.[22]

In support of its proposal, the Exchange has made the following representations:

(1) The Fund and the Shares are currently in compliance with the listing standards and other rules of the Exchange and the requirements set forth in the Prior Release.

(2) The Fund will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.600, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(3) There is no change to the Fund's investment objective.

(4) Except for the changes noted above, all other facts presented and representations made in the Prior Release remain unchanged.

This approval order is based on all of the Exchange's representations, including those set forth above; in the Notice, as modified by Amendment No. 1 thereto; in Amendment Nos. 2 and 3 to the proposed rule change; and in the Prior Release.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1, 2, and 3, is consistent with Section 6(b)(5) of the Act[23] and the rules and regulations thereunder applicable to a national securities exchange.

## IV. Solicitation of Comments on Amendment Nos. 2 and 3 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment Nos. 2 and 3 to the proposed rule change are 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–2014–107 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2014–107. 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–NYSEArca–2014–107 and should be submitted on or before May 22, 2015.

## V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3

The Commission finds good cause to approve the proposed rule change, as modified by Amendment Nos. 1, 2, and 3, prior to the thirtieth day after the date of publication of notice of the amendments in the **Federal Register**. Amendment Nos. 2 and 3 modify the proposed rule change by permitting the Fund to invest up to 20% of its assets in Private MBS/ABS. The Commission believes that the proposed rule change is consistent with the permitted allocation of such MBS and ABS holdings with respect to other issues of Managed Fund Shares previously approved by the Commission for Exchange listing and trading.[24] Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[25] to approve the proposed rule change, as modified by Amendment Nos. 1, 2, and 3, on an accelerated basis.

## VI. Conclusion

*It is therefore ordered,* pursuant to Section 19(b)(2) of the Act,[26] that the proposed rule change (SR–NYSEArca–2014–107), as modified by Amendment Nos. 1, 2, and 3, be, and it hereby is, approved on an accelerated basis.

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

[20] *See, e.g.,* Securities Exchange Act Release Nos. 74109 (Jan. 21, 2015), 80 FR 4327 (Jan. 27, 2015) (SR–NYSEArca–2014–134) (providing for similar limitations on MBS and ABS with respect to the IQ Wilshire Alternative Strategies ETF); and 70282 (Aug. 29, 2013), 78 FR 54700 (Sept. 5, 2013) (providing for similar limitations on illiquid assets with respect to the First Trust Inflation Managed Fund).

[21] *See, e.g.,* Securities Exchange Act Release Nos. 74093 (Jan. 20, 2015), 80 FR 4015 (Jan. 26, 2015) (SR–NYSEArca–2014–126) (approving the listing and trading of shares of the AdvisorShares Pacific Asset Enhanced Floating Rate ETF based on a portfolio of non-investment grade fixed income securities defined as being rated below ''Baa3,'' among other investments); and 71617 (Feb. 26, 2014), 79 FR 12257 (Mar. 4, 2014) (SR–NYSEArca–2013–135) (approving the listing and trading of shares of the db-X Ultra-Short Duration Fund based on a portfolio of investment grade fixed income securities defined as being rated ''Baa3'' or higher, among other investments).

[22] *See, e.g.,* Securities Exchange Act Release No. 67277 (Jun. 27, 2012), 80 FR 4327 (July 3, 2012) (SR–NYSEArca–2012–39) (approving the listing and trading of shares of the Global Alpha & Beta ETF based on a portfolio of other exchange-traded products that include other ETFs and closed-end funds, among other investments).

[23] 17 CFR 240.10A–3.

[24] *See supra* note 20 and accompanying text.

[25] 15 U.S.C. 78s(b)(2).

[26] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015–10160 Filed 4–30–15; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Investment Company Act Release No. 31579; File No. 812–14443]**

## Highland Funds I, et al.; Notice of Application

April 27, 2015.

**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 (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, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

**SUMMARY OF APPLICATION:** Applicants request an order that would permit (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 rather than at net asset value (''NAV''); (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; (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; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to perform creations and redemptions of Creation Units in-kind in a master-feeder structure.

**APPLICANTS:** Highland Funds I (the ''Trust''), Highland Capital Management Fund Advisors, L.P. (the ''Initial Adviser''), and SEI Investments Distribution Co. (the ''Distributor'').

**FILING DATES:** The application was filed on April 17, 2015, and amended on April 23, 2015 and April 27, 2015.

**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 22, 2015, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

**ADDRESSES:** The Commission: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: The Trust and the Initial Adviser, 200 Crescent Court, Suite 700, Dallas, TX 75201; the Distributor, One Freedom Valley Drive, Oaks, PA 19456.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Zaruba, Senior Counsel at (202) 551–6878, or David P. Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

**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 for 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 Trust is organized as a Delaware statutory trust and is registered under the Act as an open-end management investment company with multiple series.

2. The Initial Adviser is registered as investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act'') and will be the investment adviser to the Funds (defined below). Any other Adviser (defined below) will also be registered as an investment adviser under the Advisers Act. The Adviser may enter into sub-advisory agreements with one or more investment advisers to act as sub-advisers to particular Funds (each, a ''Sub-Adviser''). Any Sub-Adviser will either be registered under the Advisers Act or will not be required to register thereunder.

3. Each Trust will enter into a distribution agreement with the Distributor. The distributor for the Initial Funds (defined below) will be SEI Investments Distribution Co. The Distributor is a broker-dealer (''Broker'') registered under the Securities Exchange Act of 1934 (the ''Exchange Act'') and will act as distributor and principal underwriter of one or more of the Funds. The distributor of any Fund may be an affiliated person, as defined in section 2(a)(3) of the Act (''Affiliated Person''), or an affiliated person of an Affiliated Person (''Second-Tier Affiliate''), of that Fund's Adviser and/or Sub-Advisers. No distributor will be affiliated with any Exchange (defined below).

4. Applicants request that the order apply to the initial series of the Trust described in the application that will rely on the requested order (''Initial Funds''), as well as any additional series of the Trust and other open-end management investment companies, or series thereof, that may be created in the future (''Future Funds''), each of which will operate as an exchanged-traded fund (''ETF'') and will track a specified index that includes both long and short positions or uses a 130/30 investment strategy and is comprised of domestic or foreign equity and/or fixed income securities (each, an ''Underlying Index'').[1] Any Future Fund will (a) be advised by the Initial Advisers or an entity controlling, controlled by, or under common control with the Initial Advisers (each, an ''Adviser'') and (b) comply with the terms and conditions of the application. The Initial Funds and Future Funds, together, are the ''Funds.''[2]

5. Applicants state that a Fund may operate as a feeder fund in a master-feeder structure (''Feeder Fund''). Applicants request that the order permit a Feeder Fund to acquire shares of another registered investment company in the same group of investment companies having substantially the

[27] 17 CFR 200.30–3(a)(12).

[1] Certain of the applicants received a prior order with respect to the offering of index-based exchange-traded funds. In the Matter of Highland Capital Management, L.P., et al., Investment Company Act Release Nos. 29890 (Dec. 19, 2011) (notice) and 29918 (Jan. 17, 2012) (order) (the ''Prior Order''). The Prior Order does not apply to Long/Short Funds and 130/30 Funds (each as defined herein), and the order requested herein by applicants will only cover Long/Short Funds and 130/30 Funds.

[2] All existing entities that intend to rely on the requested order have been named as applicants. Any other existing or future entity that subsequently relies on the order will comply with the terms and conditions of the order. A Fund of Funds (as defined below) may rely on the order only to invest in Funds and not in any other registered investment company.

same investment objectives as the Feeder Fund (''Master Fund'') beyond the limitations in section 12(d)(1)(A) of the Act and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B) of the Act (''Master-Feeder Relief''). Applicants may structure certain Feeder Funds to generate economies of scale and incur lower overhead costs.[3] There would be no ability by Fund shareholders to exchange Shares of Feeder Funds for shares of another feeder series of the Master Fund.

6. Each Fund, or its respective Master Fund, will hold certain securities, currencies, other assets and other investment positions (''Portfolio Holdings'') selected to correspond generally to the performance of its Underlying Index. Certain of the Funds will be based on Underlying Indexes that will be comprised solely of equity and/or fixed income securities issued by one or more of the following categories of issuers: (i) Domestic issuers and (ii) non-domestic issuers meeting the requirements for trading in U.S. markets. Other Funds will be based on Underlying Indexes that will be comprised solely of foreign and domestic, or solely foreign, equity and/or fixed income securities (''Foreign Funds'').

7. Applicants represent that each Fund, or its respective Master Fund, will invest at least 80% of its assets (excluding securities lending collateral) in the component securities of its respective Underlying Index (''Component Securities'') and TBA Transactions,[4] and in the case of Foreign Funds, Component Securities and Depositary Receipts[5] representing Component Securities. Each Fund, or its respective Master Fund, may also invest up to 20% of its assets in certain index futures, options, options on index futures, swap contracts or other derivatives, as related to its respective Underlying Index and its Component Securities, cash and cash equivalents, other investment companies, as well as in securities and other instruments not included in its Underlying Index but which the Adviser believes will help the Fund track its Underlying Index. A Fund may also engage in short sales in accordance with its investment objective.

8. Funds will seek to track Underlying Indexes constructed using 130/30 investment strategies (''130/30 Funds'') or other long/short investment strategies (''Long/Short Funds''). Each Long/Short Fund will establish (i) exposures equal to approximately 100% of the long positions specified by the Long/Short Index[6] and (ii) exposures equal to approximately 100% of the short positions specified by the Long/Short Index. Each 130/30 Fund will include strategies that: (i) Establish long positions in securities so that total long exposure represents approximately 130% of a Fund's net assets; and (ii) simultaneously establish short positions in other securities so that total short exposure represents approximately 30% of such Fund's net assets. Each Business Day, the Adviser for each Fund will provide full portfolio transparency on the Fund's publicly available Web site (''Web site'') by making available the Fund's, or its respective Master Fund's, Portfolio Holdings before the commencement of trading of Shares on the Listing Exchange (defined below).[7] The information provided on the Web site will be formatted to be reader-friendly.

9. A Fund, or its respective Master Fund, will utilize either a replication or representative sampling strategy to track its Underlying Index. A Fund, or its respective Master Fund, using a replication strategy will invest in the Component Securities of its Underlying Index in the same approximate proportions as in such Underlying Index. A Fund, or its respective Master Fund, using a representative sampling strategy will hold some, but not necessarily all of the Component Securities of its Underlying Index. Applicants state that a Fund, or its respective Master Fund, using a representative sampling strategy will not be expected to track the performance of its Underlying Index with the same degree of accuracy as would an investment vehicle that invested in every Component Security of the Underlying Index with the same weighting as the Underlying Index. Applicants expect that each Fund will have an annual tracking error relative to the performance of its Underlying Index of less than 5%.

10. Each Fund will be entitled to use its Underlying Index pursuant to either a licensing agreement with the entity that compiles, creates, sponsors or maintains the Underlying Index (each, an ''Index Provider'') or a sub-licensing arrangement with the applicable Adviser, which will have a licensing agreement with such Index Provider.[8] A ''Self-Indexing Fund'' is a Fund for which an Affiliated Person, or a Second-Tier Affiliate, of the Trust or a Fund, of the Adviser, of any Sub-Adviser to or promoter of a Fund, or of the Distributor (each, an ''Affiliated Index Provider'') will serve as the Index Provider. In the case of Self-Indexing Funds, an Affiliated Index Provider will create a proprietary, rules-based methodology to create Underlying Indexes (each an ''Affiliated Index'').[9] Except with respect to the Self-Indexing Funds, no Index Provider is or will be an Affiliated Person, or a Second-Tier Affiliate, of the Trust or a Fund, of the Adviser, of any

[3] Operating in a master-feeder structure could also impose costs on a Feeder Fund and reduce its tax efficiency. The Feeder Fund's Board will consider any such potential disadvantages against the benefits of economies of scale and other benefits of operating within a master-feeder structure. In a master-feeder structure, the Master Fund—rather than the Feeder Fund—would generally invest its portfolio in compliance with the requested order.

[4] A ''to-be-announced transaction'' or ''TBA Transaction'' is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to settlement date.

[5] Depositary receipts representing foreign securities (''Depositary Receipts'') include American Depositary Receipts and Global Depositary Receipts. The Funds, or their respective Master Funds, may invest in Depositary Receipts representing foreign securities in which they seek to invest. Depositary Receipts are typically issued by a financial institution (a ''depositary bank'') and evidence ownership interests in a security or a pool of securities that have been deposited with the depositary bank. A Fund, or its respective Master Fund, will not invest in any Depositary Receipts that the Adviser or any Sub-Adviser deems to be illiquid or for which pricing information is not readily available. No affiliated person of a Fund, the Adviser or any Sub-Adviser will serve as the depositary bank for any Depositary Receipts held by a Fund, or its respective Master Fund.

[6] Underlying Indexes that include both long and short positions in securities are referred to as ''Long/Short Indexes.''

[7] Under accounting procedures followed by each Fund, 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.

[8] The licenses for the Self-Indexing Funds will specifically state that the Affiliated Index Provider (or in case of a sub-licensing agreement, the Adviser) must provide the use of the Underlying Indexes and related intellectual property at no cost to the Trust and the Self-Indexing Funds.

[9] The Affiliated Indexes may be made available to registered investment companies, as well as separately managed accounts of institutional investors and privately offered funds that are not deemed to be ''investment companies'' in reliance on section 3(c)(1) or 3(c)(7) of the Act for which the Adviser acts as adviser or subadviser (''Affiliated Accounts'') as well as other such registered investment companies, separately managed accounts and privately offered funds for which it does not act either as adviser or subadviser (''Unaffiliated Accounts''). The Affiliated Accounts and the Unaffiliated Accounts, like the Funds, would seek to track the performance of one or more Underlying Index(es) by investing in the constituents of such Underlying Indexes or a representative sample of such constituents of the Underlying Index. Consistent with the relief requested from section 17(a), the Affiliated Accounts will not engage in Creation Union transactions with a Fund.

Sub-Adviser to or promoter of a Fund, or of the Distributor.

11. Applicants recognize that Self-Indexing Funds could raise concerns regarding the ability of the Affiliated Index Provider to manipulate the Underlying Index to the benefit or detriment of the Self-Indexing Fund. Applicants further recognize the potential for conflicts that may arise with respect to the personal trading activity of personnel of the Affiliated Index Provider who have knowledge of changes to an Underlying Index prior to the time that information is publicly disseminated. Prior orders granted to self-indexing ETFs (''Prior Self-Indexing Orders'') addressed these concerns by creating a framework that required: (i) Transparency of the Underlying Indexes; (ii) the adoption of policies and procedures not otherwise required by the Act designed to mitigate such conflicts of interest; (iii) limitations on the ability to change the rules for index compilation and the component securities of the index; (iv) that the index provider enter into an agreement with an unaffiliated third party to act as ''Calculation Agent''; and (v) certain limitations designed to separate employees of the index provider, adviser and Calculation Agent (clauses (ii) through (v) are hereinafter referred to as ''Policies and Procedures'').[10]

12. Instead of adopting the same or similar Policies and Procedures, Applicants propose that each day that a Fund, the NYSE and the national securities exchange (as defined in section 2(a)(26) of the Act) (an ''Exchange'') on which the Fund's Shares are primarily listed (''Listing Exchange'') are open for business, including any day that a Fund is required to be open under section 22(e) of the Act (a ''Business Day''), each Self-Indexing Fund will post on its Web site, before commencement of trading of Shares on the Listing Exchange, the identities and quantities of the Portfolio Holdings that will form the basis for the Fund's calculation of its NAV at the end of the Business Day. Applicants believe that requiring Self-Indexing Funds, and their respective Master Funds, to maintain full portfolio transparency will provide an effective alternative mechanism for addressing any such potential conflicts of interest.

13. Applicants represent that each Self-Indexing Fund's Portfolio Holdings will be as transparent as the portfolio holdings of existing actively managed ETFs. Applicants observe that the framework set forth in the Prior Self-Indexing Orders was established before the Commission began issuing exemptive relief to allow the offering of actively managed ETFs.[11] Unlike passively managed ETFs, actively managed ETFs do not seek to replicate the performance of a specified index but rather seek to achieve their investment objectives by using an ''active'' management strategy. Applicants contend that the structure of actively managed ETFs presents potential conflicts of interest that are the same as those presented by Self-Indexing Funds because the portfolio managers of an actively managed ETF by definition have advance knowledge of pending portfolio changes. However, rather than requiring Policies and Procedures similar to those required under the Prior Self-Indexing Orders, Applicants believe that actively managed ETFs address these potential conflicts of interest appropriately through full portfolio transparency, as the conditions to their relevant exemptive relief require.

14. In addition, Applicants do not believe the potential for conflicts of interest raised by the Adviser's use of the Underlying Indexes in connection with the management of the Self Indexing Funds, their respective Master Funds, and the Affiliated Accounts will be substantially different from the potential conflicts presented by an adviser managing two or more registered funds. Both the Act and the Advisers Act contain various protections to address conflicts of interest where an adviser is managing two or more registered funds and these protections will also help address these conflicts with respect to the Self-Indexing Funds.[12]

15. The Adviser and any Sub-Adviser has adopted or will adopt, pursuant to Rule 206(4)–7 under the Advisers Act, written policies and procedures designed to prevent violations of the Advisers Act and the rules thereunder. These include policies and procedures designed to minimize potential conflicts of interest among the Self-Indexing Funds, their respective Master Funds, and the Affiliated Accounts, such as cross trading policies, as well as those designed to ensure the equitable allocation of portfolio transactions and brokerage commissions. In addition, the Adviser has adopted policies and procedures as required under section 204A of the Advisers Act, which are reasonably designed in light of the nature of its business to prevent the misuse, in violation of the Advisers Act or the Exchange Act or the rules thereunder, of material non-public information by the Adviser or an associated person (''Inside Information Policy''). Any Sub-Adviser will be required to adopt and maintain a similar Inside Information Policy. In accordance with the Code of Ethics[13] and Inside Information Policy of the Adviser and Sub-Advisers, personnel of those entities with knowledge about the composition of the Portfolio Deposit[14] will be prohibited from disclosing such information to any other person, except as authorized in the course of their employment, until such information is made public. In addition, an Index Provider will not provide any information relating to changes to an Underlying Index's methodology for the inclusion of component securities, the inclusion or exclusion of specific component securities, or methodology for the calculation or the return of component securities, in advance of a public announcement of such changes by the Index Provider. The Adviser will also include under Item 10.C. of Part 2 of its Form ADV a discussion of its relationship to any Affiliated Index Provider and any material conflicts of interest resulting therefrom, regardless

[10] *See, e.g.,* In the Matter of WisdomTree Investments Inc., et al., Investment Company Act Release Nos. 27324 (May 18, 2006) (notice) and 27391 (June 12, 2006) (order); In the Matter of IndexIQ ETF Trust, et al., Investment Company Act Release Nos. 28638 (Feb. 27, 2009) (notice) and 28653 (March 20, 2009) (order); Van Eck Associates Corporation, et al., et al., Investment Company Act Release Nos. 29455 (Oct. 1, 2010) (notice) and 29490 (Oct. 26, 2010) (order); and In the Matter of Guggenheim Funds Investment Advisors, LLC, et al., Investment Company Act Release Nos. 30560 (June 14, 2013) (notice) and 30598 (July 10, 2013) (order).

[11] *See, e.g.,* In the Matter of Huntington Asset Advisors, Inc., et al., Investment Company Act Release Nos. 30032 (April 10, 2012) (notice) and 30061 (May 8, 2012) (order); In the Matter of Russell Investment Management Co., et al., Investment Company Act Release Nos. 29655 (April 20, 2011) (notice) and 29671 (May 16, 2011) (order); In the Matter of Eaton Vance Management, et al., Investment Company Act Release Nos. 29591 (March 11, 2011) (notice) and 29620 (March 30, 2011) (order); and In the Matter of iShares Trust, et al., Investment Company Act Release Nos. 29543 (Dec. 27, 2010) (notice) and 29571 (Jan. 24, 2011) (order).

[12] *See, e.g.,* Rule 17j–1 under the Act and Section 204A under the Advisers Act and Rules 204A–1 and 206(4)–7 under the Advisers Act.

[13] The Adviser has also adopted or will adopt a code of ethics pursuant to Rule 17j–1 under the Act and Rule 204A–1 under the Advisers Act, which contains provisions reasonably necessary to prevent Access Persons (as defined in Rule 17j–1) from engaging in any conduct prohibited in Rule 17j–1 (''Code of Ethics'').

[14] The instruments and cash that the purchaser is required to deliver in exchange for the Creation Units it is purchasing is referred to as the ''Portfolio Deposit.''

of whether the Affiliated Index Provider is a type of affiliate specified in Item 10.

16. To the extent the Self-Indexing Funds or their respective Master Funds transact with an Affiliated Person of the Adviser or Sub-Adviser, such transactions will comply with the Act, the rules thereunder and the terms and conditions of the requested order. In this regard, each Self-Indexing Fund's board of directors or trustees (''Board'') will periodically review the Self-Indexing Fund's use of an Affiliated Index Provider. Subject to the approval of the Self-Indexing Fund's Board, the Adviser, Affiliated Persons of the Adviser (''Adviser Affiliates'') and Affiliated Persons of any Sub-Adviser (''Sub-Adviser Affiliates'') may be authorized to provide custody, fund accounting and administration and transfer agency services to the Self-Indexing Funds. Any services provided by the Adviser, Adviser Affiliates, Sub-Adviser and Sub-Adviser Affiliates will be performed in accordance with the provisions of the Act, the rules under the Act and any relevant guidelines from the staff of the Commission.

17. In light of the foregoing, Applicants believe it is appropriate to allow the Self-Indexing Funds and their respective Master Funds to be fully transparent in lieu of Policies and Procedures from the Prior Self-Indexing Orders discussed above.

18. The Shares of each Fund will be purchased and redeemed in Creation Units and generally on an in-kind basis. 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'').[15] On any given Business Day, 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, unless the Fund is Rebalancing (as defined below). In addition, the Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions)[16] 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;[17] (c) TBA Transactions, short positions, derivatives and other positions that cannot be transferred in kind[18] will be excluded from the Deposit Instruments and the Redemption Instruments;[19] (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund's portfolio;[20] or (e) for temporary periods, to effect changes in the Fund's portfolio as a result of the rebalancing of its Underlying Index (any such change, a ''Rebalancing''). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments 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 ''Cash Amount'').

19. 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 Cash Amount; (b) if, on a given Business Day, the 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, the Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash;[21] (d) if, on a given Business Day, the 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 or DTC (defined below); or (ii) in the case of Foreign Funds holding non-U.S. investments, such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if the 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 Foreign Fund holding non-U.S. investments would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[22]

20. Creation Units will consist of specified large aggregations of Shares, *e.g.,* at least 25,000 Shares, and it is expected that the initial price of a Creation Unit will range from $1 million to $10 million. All orders to purchase Creation Units must be placed with the Distributor by or through an ''Authorized Participant'' which is either (1) a ''Participating Party,'' *i.e.,* a broker-dealer or other participant in the Continuous Net Settlement System of the NSCC, a clearing agency registered with the Commission, or (2) a participant in The Depository Trust Company (''DTC'') (''DTC Participant''), which, in either case, has signed a participant agreement with the

[15] 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 of 1933 (''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.

[16] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV for the Business Day.

[17] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[18] 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.

[19] Because these instruments will be excluded from the Deposit Instruments and the Redemption Instruments, their value will be reflected in the determination of the Cash Amount (as defined below).

[20] A Fund may only use sampling for this purpose if the sample: (i) Is designed to generate performance that is highly correlated to the performance of the Fund's portfolio; (ii) consists entirely of instruments that are already included in the Fund's portfolio; and (iii) is the same for all Authorized Participants (as defined below) on a given Business Day.

[21] 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 consideration may warrant in-kind redemptions.

[22] 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).

Distributor. The Distributor will be responsible for transmitting the orders to the Funds and will furnish to those placing such orders confirmation that the orders have been accepted, but applicants state that the Distributor may reject any order which is not submitted in proper form.

21. 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 Deposit Instruments and the Redemption Instruments, as well as the estimated Cash Amount (if any), for that day. The list of Deposit Instruments and Redemption Instruments will apply until a new list is announced on the following Business Day, and there will be no intra-day changes to the list except to correct errors in the published list. Each Listing Exchange will disseminate, every 15 seconds during regular Exchange trading hours, through the facilities of the Consolidated Tape Association, an amount for each Fund stated on a per individual Share basis representing the sum of (i) the estimated Cash Amount and (ii) the current value of the Deposit Instruments.

22. Transaction expenses, including operational processing and brokerage costs, will be incurred by a Fund when investors purchase or redeem Creation Units in-kind and such costs have the potential to dilute the interests of the Fund's existing shareholders. Each Fund will impose purchase or redemption transaction fees (''Transaction Fees'') in connection with effecting such purchases or redemptions of Creation Units. With respect to Feeder Funds, the Transaction Fee would be paid indirectly to the Master Fund.[23] In all cases, such Transaction Fees will be limited in accordance with requirements of the Commission applicable to management investment companies offering redeemable securities. Since the Transaction Fees are intended to defray the transaction expenses as well as to prevent possible shareholder dilution resulting from the purchase or redemption of Creation Units, the Transaction Fees will be borne only by such purchasers or redeemers.[24] The Distributor will be responsible for delivering the Fund's prospectus to those persons acquiring Shares in Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it. In addition, the Distributor will maintain a record of the instructions given to the applicable Fund to implement the delivery of its Shares.

23. Shares of each Fund will be listed and traded individually on an Exchange. It is expected that one or more member firms of an Exchange will be designated to act as a market maker (each, a ''Market Maker'') and maintain a market for Shares trading on the Exchange. Prices of Shares trading on an Exchange will be based on the current bid/offer market. Transactions involving the sale of Shares on an Exchange will be subject to customary brokerage commissions and charges.

24. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrageurs. Market Makers, acting in their roles to provide a fair and orderly secondary market for the Shares, may from time to time find it appropriate to purchase or redeem Creation Units. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[25] The price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

25. Shares will not be individually redeemable, and owners of Shares may acquire those Shares from the Fund, or tender such Shares for redemption to the Fund, in Creation Units only. To redeem, an investor must accumulate enough Shares to constitute a Creation Unit. Redemption requests must be placed through an Authorized Participant. A redeeming investor may pay a Transaction Fee, calculated in the same manner as a Transaction Fee payable in connection with purchases of Creation Units.

26. Neither the Trust nor any Fund will be advertised or marketed or otherwise held out as a traditional open-end investment company or a ''mutual fund.'' Instead, each such Fund will be marketed as an ''ETF.'' All marketing materials that describe the features or method of obtaining, buying or selling Creation Units, or Shares traded on an Exchange, or refer to redeemability, will prominently disclose that Shares are not individually redeemable and will disclose that the owners of Shares may acquire those Shares from the Fund or tender such Shares for redemption to the Fund in Creation Units only. The Funds will provide copies of their annual and semi-annual shareholder reports to DTC Participants for distribution to beneficial owners of Shares.

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, under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(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 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. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provisions of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

*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.

[23] Applicants are not requesting relief from section 18 of the Act. Accordingly, a Master Fund may require a Transaction Fee payment to cover expenses related to purchases or redemptions of the Master Fund's shares by a Feeder Fund only if it requires the same payment for equivalent purchases or redemptions by any other feeder fund. Thus, for example, a Master Fund may require payment of a Transaction Fee by a Feeder Fund for transactions for 20,000 or more shares so long as it requires payment of the same Transaction Fee by all feeder funds for transactions involving 20,000 or more shares.

[24] Where a Fund permits an in-kind purchaser to substitute cash-in-lieu of depositing one or more of the requisite Deposit Instruments, the purchaser may be assessed a higher Transaction Fee to cover the cost of purchasing such Deposit Instruments.

[25] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or the DTC Participants.

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 owner, 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. Because Shares will not be individually redeemable, applicants request an order that would permit the Funds to register as open-end management investment companies and issue Shares that are redeemable in Creation Units only.[26] Applicants state that investors may purchase Shares in Creation Units and redeem Creation Units from each Fund. Applicants further state that because Creation Units may always be purchased and redeemed at NAV, the price of Shares on the secondary market should not vary materially from 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 that is currently being offered to the public by or through an 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, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. 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 designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution of investment company shares by eliminating price competition from dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve a Fund as a party and will not result in dilution of an investment in Shares, 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 price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

*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 state that settlement of redemptions for Foreign Funds will be contingent not only on the settlement cycle of the United States market, but also on current delivery cycles in local markets for the underlying foreign securities held by a Foreign Fund. Applicants state that the delivery cycles currently practicable for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, may require a delivery process of up to fifteen (15) calendar days.[27] Accordingly, with respect to Foreign Funds only, applicants hereby request relief under section 6(c) from the requirement imposed by section 22(e) to allow Foreign Funds to pay redemption proceeds within fifteen (15) calendar days following the tender of Creation Units for redemption.[28]

8. Applicants believe that Congress adopted section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds. Applicants propose that allowing redemption payments for Creation Units of a Foreign Fund to be made within fifteen calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants suggest that a redemption payment occurring within fifteen calendar days following a redemption request would adequately afford investor protection.

9. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect creations and redemptions of Creation Units in-kind.[29]

*Section 12(d)(1)*

10. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring securities of an investment company if such securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter and any other broker-dealer from knowingly selling the investment company's shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

11. Applicants request an exemption to permit registered management investment companies and unit investment trusts (''UITs'') that are not advised or sponsored by the Advisers and are not part of the same ''group of investment companies,'' as defined in section 12(d)(1)(G)(ii) of the Act as the Funds (such management investment companies are referred to as ''Investing Management Companies,'' such UITs are referred to as ''Investing Trusts,'' and Investing Management Companies and Investing Trusts are collectively referred to as ''Funds of Funds''), to acquire Shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter

[26] The Master Funds will not require relief from sections 2(a)(32) and 5(a)(1) because the Master Funds will issue individually redeemable securities.

[27] Certain countries in which a Fund may invest have historically had settlement periods of up to fifteen (15) calendar days.

[28] Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may otherwise have under rule 15c6–1 under the Exchange Act requiring that most securities transactions be settled within three business days of the trade date.

[29] In addition, the requested exemption from section 22(e) would only apply to in-kind redemptions by the Feeder Funds and would not apply to in-kind redemptions by other feeder funds.

for the Funds, and/or any Broker registered under the Exchange Act, to sell Shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act.

12. Each Investing Management Company will be advised by an investment adviser within the meaning of section 2(a)(20)(A) of the Act (the ''Fund of Funds Adviser'') and may be sub-advised by investment advisers within the meaning of section 2(a)(20)(B) of the Act (each a ''Fund of Funds Sub-Adviser''). Any investment adviser to an Investing Management Company will be registered under the Advisers Act. Each Investing Trust will be sponsored by a sponsor (''Sponsor'').

13. Applicants submit that the proposed conditions to the requested relief adequately address the concerns underlying the limits in sections 12(d)(1)(A) and (B), which include concerns about undue influence by a fund of funds over underlying funds, excessive layering of fees and overly complex fund structures. Applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

14. Applicants believe that neither a Fund of Funds nor a Fund of Funds Affiliate would be able to exert undue influence over a Fund.[30] To limit the control that a Fund of Funds may have over a Fund, applicants propose a condition prohibiting a Fund of Funds Adviser or Sponsor, any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor, and any investment company and any issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by a Fund of Funds Adviser or Sponsor, or any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor (''Fund of Funds Advisory Group'') from controlling (individually or in the aggregate) a Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Fund of Funds Sub-Adviser, any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Fund of Funds Sub-Adviser or any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser (''Fund of Funds Sub-Advisory Group'').

15. Applicants propose other conditions to limit the potential for undue influence over the Funds, including that no Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate (''Affiliated Underwriting''). An ''Underwriting Affiliate'' is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Fund of Funds Adviser, Fund of Funds Sub-Adviser, employee or Sponsor of the Fund of Funds, or a person of which any such officer, director, member of an advisory board, Fund of Funds Adviser or Fund of Funds Sub-Adviser, employee or Sponsor is an affiliated person (except that any person whose relationship to the Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

16. Applicants do not believe that the proposed arrangement will involve excessive layering of fees. The board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of section 2(a)(19) of the Act (''disinterested directors or trustees''), will find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Fund, or its respective Master Fund, in which the Investing Management Company may invest. In addition, under condition B.5., a Fund of Funds Adviser, or a Fund of Funds' trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund, or its respective Master Fund, under rule 12b–1 under the Act) received from a Fund by the Fund of Funds Adviser, trustee or Sponsor or an affiliated person of the Fund of Funds Adviser, trustee or Sponsor, other than any advisory fees paid to the Fund of Funds Adviser, trustee or Sponsor or its affiliated person by a Fund, in connection with the investment by the Fund of Funds in the Fund. Applicants state that any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.[31]

17. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that no Fund, nor its respective Master Fund, will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Fund, or its respective Master Fund, to purchase shares of other investment companies for short-term cash management purposes or pursuant to the Master-Feeder Relief. To ensure a Fund of Funds is aware of the terms and conditions of the requested order, the Fund of Funds will enter into an agreement with the Fund (''FOF Participation Agreement''). The FOF Participation Agreement will include an acknowledgement from the Fund of Funds that it may rely on the order only to invest in the Funds and not in any other investment company.

18. Applicants also note that a Fund may choose to reject a direct purchase of Shares in Creation Units by a Fund of Funds. To the extent that a Fund of Funds purchases Shares in the secondary market, a Fund would still retain its ability to reject any initial investment by a Fund of Funds in excess of the limits of section 12(d)(1)(A) by declining to enter into a FOF Participation Agreement with the Fund of Funds.

19. Applicants also are seeking the Master-Feeder Relief to permit the Feeder Funds to perform creations and redemptions of Shares in-kind in a master-feeder structure. Applicants assert that this structure is substantially identical to traditional master-feeder structures permitted pursuant to the exception provided in section 12(d)(1)(E) of the Act. Section 12(d)(1)(E) provides that the percentage limitations of section 12(d)(1)(A) and (B) shall not apply to a security issued by an investment company (in this case, the shares of the applicable Master Fund) if, among other things, that security is the only investment security held by the investing investment company (in this case, the Feeder

[30] A ''Fund of Funds Affiliate'' is a Fund of Funds Adviser, Fund of Funds Sub-Adviser, Sponsor, promoter, and principal underwriter of a Fund of Funds, and any person controlling, controlled by, or under common control with any of those entities. A ''Fund Affiliate'' is an investment adviser, promoter, or principal underwriter of a Fund and any person controlling, controlled by or under common control with any of these entities.

[31] Any references to NASD Conduct Rule 2830 include any successor or replacement FINRA rule to NASD Conduct Rule 2830.

Fund). Applicants believe the proposed master-feeder structure complies with section 12(d)(1)(E) because each Feeder Fund will hold only investment securities issued by its corresponding Master Fund; however, the Feeder Funds may receive securities other than securities of its corresponding Master Fund if a Feeder Fund accepts an in-kind creation. To the extent that a Feeder Fund may be deemed to be holding both shares of the Master Fund and other securities, applicants request relief from section 12(d)(1)(A) and (B). The Feeder Funds would operate in compliance with all other provisions of section 12(d)(1)(E).

**Sections 17(a)(1) and (2) of the Act**

20. Sections 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, from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' of another person to include (a) 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, (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled or held with the power to vote by the other person, and (c) 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'' as the power to exercise a controlling influence over the management or policies of a company, and provides that a control relationship will be presumed where one person owns more than 25% of a company's voting securities. The Funds may be deemed to be controlled by the Adviser or an entity controlling, controlled by or under common control with the 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 the Adviser or an entity controlling, controlled by or under common control with the Adviser (an ''Affiliated Fund''). Any investor, including Market Makers, owning 5% or holding in excess of 25% of the Trust or such Funds, may be deemed affiliated persons of the Trust or such Funds. In addition, an investor could own 5% or more, or in excess of 25% of the outstanding shares of one or more Affiliated Funds making that investor a Second-Tier Affiliate of the Funds.

21. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act pursuant to sections 6(c) and 17(b) of the Act to permit persons that are Affiliated Persons of the Funds, or Second-Tier Affiliates of the Funds, solely by virtue of one or more of the following: (a) Holding 5% or more, or in excess of 25%, of the outstanding Shares of one or more Funds; (b) an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds, to effectuate purchases and redemptions ''in-kind.''

22. Applicants assert that no useful purpose would be served by prohibiting such affiliated persons 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 of Creation Units will be effected in exactly the same manner for all purchases and redemptions, regardless of size or number. There will be no discrimination between purchasers or redeemers. Deposit Instruments and Redemption Instruments for each Fund will be valued in the identical manner as those Portfolio Holdings currently held by such Fund and the valuation of the Deposit Instruments and Redemption Instruments will be made in an identical manner regardless of the identity of the purchaser or redeemer. Applicants do not believe that ''in-kind'' purchases and redemptions will result in abusive self-dealing or overreaching, but rather assert that such procedures will be implemented consistently with each Fund's objectives and with the general purposes of the Act. Applicants believe that ''in-kind'' purchases and redemptions will be made on terms reasonable to applicants and any affiliated persons because they will be valued pursuant to verifiable objective standards. The method of valuing Portfolio Holdings held by a Fund is identical to that used for calculating ''in-kind'' purchase or redemption values and therefore creates no opportunity for affiliated persons or Second-Tier Affiliates of applicants to effect a transaction detrimental to the other holders of Shares of that Fund. Similarly, applicants submit that, by using the same standards for valuing Portfolio Holdings held by a Fund as are used for calculating ''in-kind'' redemptions or purchases, the Fund will ensure that its NAV will not be adversely affected by such securities transactions. Applicants also note that the ability to take deposits and make redemptions ''in-kind'' will help each Fund to track closely its Underlying Index and therefore aid in achieving the Fund's objectives.

23. Applicants also seek relief under sections 6(c) and 17(b) from section 17(a) to permit a Fund that is an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds to sell its Shares to and redeem its Shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[32] Applicants state that the terms of the transactions are fair and reasonable and do not involve overreaching. Applicants note that any consideration paid by a Fund of Funds for the purchase or redemption of Shares directly from a Fund will be based on the NAV of the Fund.[33] Applicants believe that any proposed transactions directly between the Funds and Funds of Funds will be consistent with the policies of each Fund of Funds. The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the investment restrictions of any such Fund of Funds and will be consistent with the investment policies set forth in the Fund of Funds' registration statement. Applicants also state that the proposed transactions are consistent with the general purposes of the Act and are appropriate in the public interest.

24. To the extent that a Fund operates in a master-feeder structure, applicants also request relief permitting the Feeder Funds to engage in in-kind creations and redemptions with the applicable Master Fund. Applicants state that the customary section 17(a)(1) and 17(a)(2)

[32] Although applicants believe that most Funds of Funds will purchase Shares in the secondary market and will not purchase Creation Units directly from a Fund, a Fund of Funds might seek to transact in Creation Units directly with a Fund that is an affiliated person of a Fund of Funds. To the extent that purchases and sales of Shares occur in the secondary market and not through principal transactions directly between a Fund of Funds and a Fund, relief from section 17(a) would not be necessary. However, the requested relief would apply to direct sales of Shares in Creation Units by a Fund to a Fund of Funds and redemptions of those Shares. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an affiliated person, or an affiliated person of an affiliated person of a Fund of Funds because the Adviser or an entity controlling, controlled by or under common control with the Adviser provides investment advisory services to that Fund of Funds.

[33] Applicants acknowledge that the receipt of compensation by (a) an affiliated person of a Fund of Funds, or an affiliated person of such person, for the purchase by the Fund of Funds of Shares of a Fund or (b) an affiliated person of a Fund, or an affiliated person of such person, for the sale by the Fund of its Shares to a Fund of Funds, may be prohibited by section 17(e)(1) of the Act. The FOF Participation Agreement also will include this acknowledgment.

relief would not be sufficient to permit such transactions because the Feeder Funds and the applicable Master Fund could also be affiliated by virtue of having the same investment adviser. However, applicants believe that in-kind creations and redemptions between a Feeder Fund and a Master Fund advised by the same investment adviser do not involve ''overreaching'' by an affiliated person. Such transactions will occur only at the Feeder Fund's proportionate share of the Master Fund's net assets, and the distributed securities will be valued in the same manner as they are valued for the purposes of calculating the applicable Master Fund's NAV. Further, all such transactions will be effected with respect to pre-determined securities and on the same terms with respect to all investors. Finally, such transaction would only occur as a result of, and to effectuate, a creation or redemption transaction between the Feeder Fund and a third-party investor. Applicants believe that the terms of the proposed transactions are reasonable and fair and do not involve overreaching on the part of any person concerned, the proposed transactions are consistent with the policy of each Fund and will be consistent with the investment objectives and policies of each Fund of Funds, and the proposed transactions are consistent with the general purposes of the Act.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

**A. ETF Relief**

1. The requested relief, other than the section 12(d)(1) Relief and the section 17 relief related to a master-feeder structure, will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based ETFs.

2. As long as a Fund operates in reliance on the requested order, Shares of such Fund will be listed on an Exchange.

3. Neither the Trust 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 Shares are not individually redeemable and that owners of Shares may acquire those Shares from the Fund and tender those Shares for redemption to a Fund in Creation Units only.

4. The Web site, 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 the midpoint of the bid/ask spread at the time of the calculation of such NAV (''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

5. Each Fund will post on the Web site on each Business Day, before commencement of trading of Shares on the Exchange, the Fund's, or its respective Master Fund's, Portfolio Holdings.

6. Neither the Adviser nor any Sub-Adviser to a Self-Indexing Fund, directly or indirectly, will cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Self-Indexing Fund) to acquire any Deposit Instrument for a Self-Indexing Fund, or its respective Master Fund, through a transaction in which the Self-Indexing Fund, or its respective Master Fund, could not engage directly.

**B. Section 12(d)(1) Relief**

1. The members of a Fund of Funds' Advisory Group will not control (individually or in the aggregate) a Fund, or its respective Master Fund, within the meaning of section 2(a)(9) of the Act. The members of a Fund of Funds' Sub-Advisory Group will not control (individually or in the aggregate) a Fund, or its respective Master Fund, within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of a Fund, the Fund of Funds' Advisory Group or the Fund of Funds' Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of a Fund, it will vote its Shares of the Fund in the same proportion as the vote of all other holders of the Fund's Shares. This condition does not apply to the Fund of Funds' Sub-Advisory Group with respect to a Fund, or its respective Master Fund, for which the Fund of Funds' Sub-Adviser or a person controlling, controlled by or under common control with the Fund of Funds' Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Fund of Funds or Fund of Funds Affiliate will cause any existing or potential investment by the Fund of Funds in a Fund to influence the terms of any services or transactions between the Fund of Funds or Fund of Funds Affiliate and the Fund, or its respective Master Fund, or a Fund Affiliate.

3. The board of directors or trustees of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to ensure that the Fund of Funds Adviser and Fund of Funds Sub-Adviser are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or a Fund of Funds Affiliate from a Fund, or its respective Master Fund, or Fund Affiliate in connection with any services or transactions.

4. Once an investment by a Fund of Funds in the securities of a Fund exceeds the limits in section 12(d)(1)(A)(i) of the Act, the Board of the Fund, or its respective Master Fund, including a majority of the directors or trustees who are not ''interested persons'' within the meaning of section 2(a)(19) of the Act (''non-interested Board members''), will determine that any consideration paid by the Fund, or its respective Master Fund, to the Fund of Funds or a Fund of Funds Affiliate in connection with any services or transactions: (i) Is fair and reasonable in relation to the nature and quality of the services and benefits received by the Fund, or its respective Master Fund; (ii) is within the range of consideration that the Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between a Fund, or its respective Master Fund, and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund, or its respective Master Fund, under rule 12b-l under the Act) received from a Fund, or its respective Master Fund, by the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, or an affiliated person of the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, other than any advisory fees paid to the Fund of Funds Adviser, trustee or Sponsor of an Investing Trust, or its affiliated person by the Fund, or its respective Master Fund, in connection with the

investment by the Fund of Funds in the Fund. Any Fund of Funds Sub-Adviser will waive fees otherwise payable to the Fund of Funds Sub-Adviser, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from a Fund, or its respective Master Fund, by the Fund of Funds Sub-Adviser, or an affiliated person of the Fund of Funds Sub-Adviser, other than any advisory fees paid to the Fund of Funds Sub-Adviser or its affiliated person by the Fund, or its respective Master Fund, in connection with the investment by the Investing Management Company in the Fund made at the direction of the Fund of Funds Sub-Adviser. In the event that the Fund of Funds Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Investing Management Company.

6. No Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to a Fund) will cause a Fund, or its respective Master Fund, to purchase a security in any Affiliated Underwriting.

7. The Board of a Fund, or its respective Master Fund, including a majority of the non-interested Board members, will adopt procedures reasonably designed to monitor any purchases of securities by the Fund, or its respective Master Fund, in an Affiliated Underwriting, once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Fund of Funds in the Fund. The Board will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Fund, or its respective Master Fund; (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Fund, or its respective Master Fund, in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to ensure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of the Fund.

8. Each Fund, or its respective Master Fund, will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by a Fund of Funds in the securities of the Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the Board's determinations were made.

9. Before investing in a Fund in excess of the limit in section 12(d)(1)(A), a Fund of Funds and the applicable Trust will execute a FOF Participation Agreement stating without limitation that their respective boards of directors or trustees and their investment advisers, or trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Shares of a Fund in excess of the limit in section 12(d)(1)(A)(i), a Fund of Funds will notify the Fund of the investment. At such time, the Fund of Funds will also transmit to the Fund a list of the names of each Fund of Funds Affiliate and Underwriting Affiliate. The Fund of Funds will notify the Fund of any changes to the list of the names as soon as reasonably practicable after a change occurs. The Fund and the Fund of Funds will maintain and preserve a copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Fund, or its respective Master Fund, in which the Investing Management Company may invest. These findings and their basis will be fully recorded in the minute books of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Fund, or its respective Master Fund, will acquire securities of an investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent (i) the Fund, or its respective Master Fund, acquires securities of another investment company pursuant to exemptive relief from the Commission permitting the Fund, or its respective Master Fund, to acquire securities of one or more investment companies for short-term cash management purposes or (ii) the Fund acquires securities of the Master Fund pursuant to the Master-Feeder Relief.

For the Commission, by the Division of Investment Management, under delegated authority.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015–10176 Filed 4–30–15; 8:45 am]

**BILLING CODE 8011–01–P**

## SMALL BUSINESS ADMINISTRATION

### Data Collection Available for Public Comments

**ACTION:** 60-day notice and request for comments.

**SUMMARY:** The Small Business Administration (SBA) intends to request approval from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) of 1995 44 U.S.C Chapter 35 requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

**DATES:** Submit comments on or before June 30, 2015.

**ADDRESSES:** Send all comments to Brittany Borg, Contracting Officer Representative, Office of Entrepreneurial Development, U.S. Small Business Administration, 409 3rd

Street SW., Suite 6200, Washington, DC 20416.

**FOR FURTHER INFORMATION CONTACT:** Brittany Borg, Contracting Officer Representative, 202–401–1354, *oedsurvey@sba.gov* or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov*.

**SUPPLEMENTARY INFORMATION:** This is a request for the collection of new information.

In October 1 2014, the Small Business Administration (SBA)'s Office of Entrepreneurial Development (OED) began the ScaleUp America initiative to expand the delivery of proven best practices in entrepreneurship education to reach more growth-oriented small business owners. Through this initiative, organizations in eight communities across the U.S. have been selected to deliver targeted and intensive assistance to established, growth-oriented small businesses and entrepreneurs. ScaleUp program goals include the growth of participating businesses, the strengthening of local entrepreneurial ecosystems (*e.g.* the network of supportive resources available to the entrepreneur), and the creation of jobs and economic growth in targeted communities.

SBA is conducting an evaluation of the ScaleUp America initiative to assess the education services provided to the participants, the effect of the assistance on achieving the business goals of the participants, participant satisfaction with the assistance, and lessons learned and recommendations provided by the participants. Through the quarterly and annual reports provided by ScaleUp administrators, SBA has the ability to collect some data on the participants and program activities. However, in order to develop a more systematic analysis on the full range of topics mentioned above, including the participants' feedback, SBA needs to collect survey and interview data from participants who attended the program, as well as from individual entrepreneurs who are recruited as members of a community-specific comparison group.

Specifically, SBA proposes the use of four instruments for data collection and analysis. These instruments are: (1) Participant Intake Survey, (2) Comparison Group Member Intake Survey and (3) Participant Follow-up Survey. SBA plans to administer each of these survey instruments to more than nine individuals. In addition, SBA plans to interview two participants or community members in each of the eight ScaleUp communities regarding program impact and successes or challenges.

Each of the proposed surveys will be administered electronically and will contain both open- and close-ended questions. The types of information that will be collected in the instruments can be found in the ''Summary of Information Collection'' section below. Quantitative analysis (the primary method of data analysis for the survey data) and qualitative analysis (the primary method of data analysis for the interview data) will be used on the data collected. Quantitative analysis will consist of univariate and multivariate statistical analyses, while qualitative analysis will consist of establishing clear rules for interpretation and finding themes in the qualitative data. The information collected and analyzed from these instruments will contribute to performance metrics and program goals, as well as recommendations on improving program practices.

**(a) Solicitation of Public Comments**

SBA is requesting comments on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information collected.

**(b) Summary of Information Collection**

BURDEN ESTIMATES FOR SCALEUP DATA COLLECTION

| | Number of: | | Burden per (minutes): | | Total burden (hours) |
|---|---|---|---|---|---|
| | Respondents | Non-respondents | Respondents | Non-respondents | |
| Total | 880 | 1680 | | | 520.0 |
| Participant intake survey | 272 | 0 | 20 | 0 | 90.7 |
| Comparison group member intake survey | 320 | 1680 | 25 | 7 | 329.3 |
| Participant follow-up survey | 272 | 0 | 20 | 0 | 90.7 |
| ScaleUp and community member interviews | 16 | 0 | 35 | 5 | 9.3 |

**Curtis B. Rich,**

*Management Analyst.*

[FR Doc. 2015–10214 Filed 4–30–15; 8:45 am]

BILLING CODE 8025–01–P

## SMALL BUSINESS ADMINISTRATION

### Data Collection Available for Public Comments

**ACTION:** 60-day notice and request for comments.

**SUMMARY:** The Small Business Administration (SBA) intends to request approval from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. chapter 35 requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

**DATES:** Submit comments on or before June 30, 2015.

**ADDRESSES:** Send all comments to Erin Kelley, Director of Research & Policy, National Women's Business Council, Small Business Administration, 5th Floor, Washington, DC 20416 or via email at *erin.kelley@nwbc.gov.*

**FOR FURTHER INFORMATION CONTACT:** Erin Kelley, Director of Research & Policy, National Women's Business Council, 202 205–6826, *erin.kelley@nwbc.gov,* or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov*

**SUPPLEMENTARY INFORMATION:** The National Women's Business Council (NWBC) is a non-partisan federal advisory council that serves as an independent source of advice and counsel to the President, Congress, and the Small Business Administration on economic issues of importance to women business owners. Members of the Council are prominent women business owners and leaders of women' business organizations.

As part of NWBC's outreach and engagement with women business owners, NWBC would like to collect information on three populations:

Attendees of public meetings; successful women business owners; and attendees of research webinars.

For the public meeting data collection, the goal is to understand the demographics of the NWBC audience and their reasons for engaging with the NWBC, in order to best cater the material and programming for that specific audience, and produce meaningful and relevant content for future programming. The NWBC also intends to stay in contact with this audience, as they are important stakeholders. The information collected from this audience will enable us to achieve this goal.

For the research webinars, the goal is to do market research and understand the marketplace of researchers that may bid on NWBC research contracting opportunities, in order to cultivate the marketplace with the intention of increasing the quality of NWBC research. The NWBC also intends to stay in contact with this audience, as they are important stakeholders. The information collected from this audience will enable us to achieve this goal.

For the successful women business owners segment, the goal of this project is to collect and amplify success stories in order to raise the visibility of women business owners. This goal is in accordance with an NWBC recommendation, which reads as follows:

*There should be greater and regular recognition of successful women in business. Research has shown that role models are an important factor in an individual's decision to pursue entrepreneurship. Media attention tends to focus on men entrepreneurs; increasing the visibility and profile of successful women entrepreneurs will normalize the idea of women founding and leading companies.*

The information collected from this audience will enable us to achieve this goal and also take action on one of our own recommendations.

The surveys will consist of three separate questionnaires targeting attendees of NWBC events, attendees of research webinars, and women business owners. Each questionnaire will take between 5 and 20 minutes to complete (see below for the estimated burden analysis of each questionnaire). The survey questions will explore a range of issues, including:

- Public Meeting Attendees: Demographics, geography, contact information, type of employment (federal employee, press, researcher, business owner).
- Research Webinar Attendees: Demographic information, subject matter expertise, company/organization information, hot topics in the attendees' fields of expertise.
- Women Business Owners: Demographics information, business information, contact information, questions on motivation, attitude, success, and overcoming challenges.

The data from the survey will be used to cultivate an audience and understand their needs so as to make more relevant policy recommendations; inform outreach strategy to potential vendors of NWBC research; and increase the visibility of successful women business owners and inspire others.

**Solicitation of Public Comments**

SBA is requesting comments on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

**Summary of Information Collection**

*Title:* NWBC Public Meeting Registration.

*Description of Respondents:* Attendees of NWBC events; attendees of research webinars; subjects of role modeling profiles.

*Form Number:* N/A.

*Total Estimated Annual Responses:* 800 (600 from NWBC events; 100 from role modeling project; and 100 from research webinar attendees).

*Total Estimated Annual Hour Burden:* 90 hours total.

| | Event attendees | | Success stories | Total (hours) |
|---|---|---|---|---|
| | NWBC | Research | | |
| Estimated survey hour burden | 5 minutes | 5 minutes | 20 minutes. | |
| Sample population hour burden estimate | 50 hours | 6.25 hours | 33.33 hours | 90 |

**Curtis B. Rich,**

*Management Analyst.*

[FR Doc. 2015–10258 Filed 4–30–15; 8:45 am]

BILLING CODE 8025–01–P

## DEPARTMENT OF STATE

**[Public Notice: 9122]**

### In the Matter of the Designation of Hussein Atris, Also Known as Atris Hussein as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Hussein Atris, also known as Atris Hussein, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: April 22, 2015.

**John F. Kerry,**

*Secretary of State.*

[FR Doc. 2015–10228 Filed 4–30–15; 8:45 am]

BILLING CODE 4710–AD–P

## DEPARTMENT OF STATE

**[Public Notice 9123]**

### Culturally Significant Objects Imported for Exhibition Determinations: ''Highlights of the Keir Collection of Art of the Islamic World'' and Related Keir Collection Exhibitions

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to

the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that objects to be included in the ''Highlights of the Keir Collection of Art of the Islamic World'' and related Keir Collection exhibitions, imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Dallas Museum of Art, Dallas, TX, and at possible additional exhibitions or venues yet to be determined, from on about September 18, 2015, until on or about May 4, 2020, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** For further information, including a list of the objects covered under this notice, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: April 24, 2015.

**Kelly Keiderling,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 2015–10231 Filed 4–30–15; 8:45 am]

BILLING CODE 4710–05–P

## DEPARTMENT OF STATE

**[Public Notice: 9121]**

### In the Matter of the Designation of Hassan el-Hajj Hassan, Also Known as Hassan El-Hajj Hassan, Also Known as Hassan El Hajj Hassan, as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Hassan el-Hajj Hassan, also known as Hassan El-Hajj Hassan, also known as Hassan El Hajj Hassan, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: April 22, 2015.

**John F. Kerry,**

*Secretary of State.*

[FR Doc. 2015–10236 Filed 4–30–15; 8:45 am]

BILLING CODE 4710–10–P

## DEPARTMENT OF STATE

**[Public Notice 9120]**

### In the Matter of the Designation of Meliad Farah Also Known as Hussein Also Known as Hussein Hussein as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Meliad Farah, also known as Hussein, also known as Hussein Hussein, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: April 22, 2015.

**John F. Kerry,**

*Secretary of State.*

[FR Doc. 2015–10233 Filed 4–30–15; 8:45 am]

BILLING CODE 4710–10–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Notice of Availability for the Cal Black Memorial Airport Final Supplemental Environmental Impact Statement (Draft SEIS) and Section 4(f) Evaluation

**AGENCY:** Federal Aviation Administration (FAA), U.S. National Park Service (NPS) and Bureau of Land Management (BLM) are cooperating agencies by virtue of their jurisdictional authority and/or resource management responsibilities.

**ACTION:** Notice of availability.

**SUMMARY:** In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) and Council on Environmental Quality regulations (40 CFR part 1500–1508), the Federal Aviation Administration announces the availability of the Final Supplemental Environmental Impact Statement (Final SEIS) and Section 4(f) Evaluation for the Cal Black Memorial Airport. The Section 4(f) Evaluation was prepared pursuant to Section 4(f) of the Department of Transportation Act of 1966 (recodified at 49 U.S.C. 303(c)).

**DATES:** The Federal Aviation Administration will not issue a final decision on the Cal Black Memorial Airport project for a minimum of 30 days after the date that the U.S. Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**.

**ADDRESSES:** Copies of the Final SEIS may be viewed during regular business hours at the following locations:

1. Federal Aviation Administration Airports Division, Suite 315, 1601 Lind Avenue SW., Renton, WA 98057
2. Federal Aviation Administration, Airports District Office, Suite 224, 26805 East 68th Avenue, Denver, CO 80249
3. San Juan County Courthouse, County Executive Office, 117 S Main, Monticello, Utah 84535

4. Web site: *http://halls.crossing.airportnetwork.com/*.

**FOR FURTHER INFORMATION CONTACT:** Janell Barrilleaux, Environmental Program Manager, Federal Aviation Administration Airports Division, Northwest Mountain Region, 1601 Lind Avenue SW., Renton, WA 98057. Mrs. Barrilleaux may be contacted during business hours at (425) 227–2611 (phone), (425) 227–1600 (fax), or via email at *Janell.Barrilleaux@faa.gov.*

**SUPPLEMENTARY INFORMATION:** The Northwest Mountain Region of the Federal Aviation Administration (FAA) as lead agency and the National Park Service (NPS) and Bureau of Land Management (BLM) as cooperating agencies have prepared a Draft Supplemental Environmental Impact Statement (Draft SEIS) and Section 4(f) Evaluation to address issues arising from the 1993 Tenth Circuit U.S. Court of Appeals Decision concerning the development of Cal Black Memorial Airport. This Draft SEIS and Section 4(f) Evaluation does not involve any new development or project at the airport. The Cal Black Memorial Airport opened in April 1992.

Halls Crossing Airport was located within the boundary of the Glen Canyon National Recreation Area, a unit of the National Park Service (NPS). Due to safety issues with that airport, an Environmental Impact Statement (EIS) was prepared concerning the development of a replacement airport. In 1990, the FAA issued a Draft and Final EIS for the development of a replacement airport. In August 1990, the FAA issued a Record of Decision (ROD) approving the development of Cal Black Memorial Airport. The FAA determined in the ROD that the use of the BLM lands upon which the airport would be built was reasonably necessary for the project. Accordingly, the BLM issued a Patent for the airport land to San Juan County on September 25, 1990. In reaching its approval, the FAA determined that no significant impacts would result from the new airport to the recreational experience of visitors to the recreational area.

In 1990, the National Parks and Conservation Association (NPCA), et al brought suit against the FAA concerning the adequacy of the EIS and the adequacy of the BLM Plan Amendment and land transfer process. In its July 7, 1993 decision, the Tenth Circuit of the U.S. Court of Appeals remanded the EIS back to the FAA and BLM for further environmental analysis of aircraft noise impacts to the recreational use of public lands and the BLM's plan amendment and transfer of land.

On November 17, 2008 the BLM issued the Monticello Field Office Record of Decision and Approved Resource Management Plan. The document provides guidance for the management of Federal lands administered by the BLM in San Juan County and a small portion of Grant County in southeast Utah and includes provisions for the disposal of the Cal Black Memorial Airport property.

FAA prepared a Draft SEIS and Section 4(f) Evaluation for the Replacement Airport at Halls Crossing to address the requirements of the U.S. Court of Appeals' findings. The scope of the Draft SEIS and Section 4(f) Evaluation included: (1) The measurement of actual aircraft noise levels in GCNRA and visitor survey, (2) an updated evaluation of existing and future aircraft noise levels; (3) a Section 4(f) evaluation using the updated noise analysis; and (4) an analysis on potential cumulative effects. The Draft SEIS was made available for a 45-day public review and comment period on December 12, 2014. The comment period included an opportunity to request a public hearing; however, no requests for a hearing were received. Comments were received by various parties and an errata sheet was prepared to identify changes that were made to the Draft SEIS in response to the public input. Additionally, Appendix J was prepared to document each comment received as well as FAA's response to each comment. These additional documents, in combination with the Draft SEIS, constitute the Final SEIS for the Replacement Airport at Halls Crossing.

Issued in Renton, Washington April 27, 2015.

**Sarah P. Dalton,**

*Division Manager, Airports Division, Northwest Mountain Region.*

[FR Doc. 2015–10240 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2015–0113]**

### Parts and Accessories Necessary for Safe Operation; Application for an Exemption From the Entertainer Motorcoach Council

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of application for exemption; request for comments.

**SUMMARY:** FMCSA requests public comment on an application for exemption from the Entertainer Motorcoach Council (EMC) to allow its members to operate certain vehicles that do not meet the emergency exit requirements in the Federal Motor Carrier Safety Regulations (FMCSRs). The FMCSRs require buses with a gross vehicle weight rating (GVWR) of more than 10,000 pounds, manufactured on or after September 1, 1994, to meet the emergency exit requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 217, ''Bus Emergency exits and window retention and release'' in effect on the date of manufacture. FMVSS No. 217 requires side exits and at least one rear exit, but when the bus configuration precludes installation of an accessible rear exit, a roof exit is required in the rear half of the bus to provide a means of egress when the bus is overturned on either side. EMC believes that while certain ''Entertainer Coaches'' do not have a rear or roof exit, the emergency exit windows at the rear sides of the vehicle that open manually and provide openings large enough to admit unobstructed passage provide an equivalent level of safety.

**DATES:** Comments must be received on or before June 1, 2015.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2015–0113 using any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the instructions for submitting comments on the Federal electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Ground Floor, Room W12–140, DOT Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday–Friday, except Federal holidays.

*Instructions:* All submissions must include the Agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the exemption process, see the ''Public Participation'' heading below. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the ''Privacy Act'' heading for further information.

*Docket:* For access to the docket to read background documents or

comments received, go to *http://www.regulations.gov* or to Room W12–140, DOT Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy Act:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

*Public participation:* The *http://www.regulations.gov* Web site is generally available 24 hours each day, 365 days each year. You may find electronic submission and retrieval help and guidelines under the ''help'' section of the *http://www.regulations.gov* Web site as well as the DOT's *http://docketsinfo.dot.gov* Web site. If you would like notification that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgment page that appears after submitting comments online.

**FOR FURTHER INFORMATION CONTACT:** Mr. Luke W. Loy, Vehicle and Roadside Operations Division, Office of Bus and Truck Standards and Operations, MC–PSV, (202) 366–0676; Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

**SUPPLEMENTARY INFORMATION:**

## Background

Section 4007 of the Transportation Equity Act for the 21st Century (TEA–21) [Pub. L. 105–178, June 9, 1998, 112 Stat. 401] amended 49 U.S.C. 31315 and 31136(e) to provide authority to grant exemptions from the FMCSRs. On August 20, 2004, FMCSA published a final rule (69 FR 51589) implementing section 4007. Under this rule, FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public with an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to or greater than the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)). If the Agency denies the request, it must state the reason for doing so. If the decision is to grant the exemption, the notice must specify the person or class of persons receiving the exemption and the regulatory provision or provisions from which an exemption is granted. The notice must specify the effective period of the exemption (up to 2 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.315(c) and 49 CFR 381.300(b)).

## EMC Application for Exemption

EMC applied for an exemption from 49 CFR 393.62(a) to allow motor carriers to operate certain ''Entertainer Coaches'' that do not comply with the regulation's emergency exit requirements. A copy of the application is included in the docket referenced at the beginning of this notice.

Section 393.62(a) of the FMCSRs requires buses with a GVWR of more than 10,000 pounds, manufactured on or after September 1, 1994, to meet the emergency exit requirements of FMVSS No. 217 in effect on the date of manufacture. FMVSS No. 217 requires all buses (other than school buses) to provide unobstructed openings for emergency exit which collectively amount, in total square centimeters, to at least 432 times the number of designated seating positions on the bus. At least 40 percent of the total required area of unobstructed openings shall be provided on each side of a bus. However, in determining the total unobstructed openings provided by a bus, no emergency exit, regardless of its area, shall be credited with more than 3,458 square centimeters of the total area requirement.

For buses with a GVWR of more than 10,000 pounds, FMVSS No. 217 requires that the unobstructed openings requirements be met by providing side exits and at least one rear exit. The rear exit must meet the requirements of S5.3–S5.5 of the standard when the bus is upright and when the bus is overturned on either side, with the occupant standing facing the exit. When the bus configuration precludes installation of an accessible rear exit, a roof exit that meets the requirements of S5.3–S5.5 when the bus is overturned on either side, with the occupant standing facing the exit, shall be provided in the rear half of the bus.

Neither the FMVSSs nor the FMCSRs define the term ''Entertainer Coach.'' In its application, EMC describes these vehicles as ''motor vehicles constructed on a bus or MPV [multipurpose passenger vehicle] chassis which provide temporary residential accommodations, as evidenced by the presence of at least four of the following facilities: Cooking, refrigeration, self-contained bathroom, heating and/or air conditioning, a potable water supply including a faucet and sink, and a separate 110–125 volt electric power supply. This definition generally tracks the definition of 'motor home' in the FMVSS and appropriately describes coaches that are built as temporary residential accommodations for the entertainment industry.''

In support of its application, EMC states:

> EMC seeks this exemption because the rear exit and roof hatch requirements in FMVSS 217 and FMCSR 393.62(a) preclude the efficient and effective operation of Entertainer Coaches. As required by 49 CFR part 381.310(c)(5), Entertainer Coaches provide an equivalent level of safety when equipped with emergency exit windows at the rear sides of the vehicle that open manually and provide openings large enough to admit unobstructed passage. Entertainer Coaches are designed and used to provide temporary residential accommodations and, because the occupants are celebrities, their families and their staff, require an additional level of security to ensure security and protection for their occupants.
>
> The requirement for rear exits in buses over 10,000 lbs. GVWR is intended to ensure a sufficient amount of rear egress for vehicles that carry a large number of passengers. The typical motorcoach is 45 feet in length and carry as many as 59 passengers. Entertainer Coaches, in contrast, typically carry less than 15 passengers, and many carry less than 10 passengers. EMC recognizes the importance of assuring access through the rear of the vehicles, even when the number of passengers is small. Such egress, however is readily available—as applied to Entertainer Coaches—by the emergency exit windows that come standard on the chassis generally used by the Entertainer Coach industry, the Prevost Entertainer 2000. Those windows allow for an egress area of 17″ tall by 24″ wide. The Prevost roof hatch allows for a similar egress area, 23″ x 23″. As a practical matter, the egress area is equivalent. As a result, Entertainer Coaches with emergency exit windows offer an equivalent level of safety as those with a roof hatch . . .
>
> Entertainer Coaches have an exemplary safety experience. Unlike the typical motorcoach passengers, these vehicle occupants are well acquainted with the vehicle. In particular, they are fully aware of the location and need for fast exit in the event of an emergency. Although fires can and do occur on these vehicles, the small number of occupants ensures safe exit from either the front or the back of the vehicle without the need for additional roof hatches. Such fires, furthermore, typically come from the back of the bus and occur when the bus is upright, further offsetting the practical need for a rear exit that meets the specific requirements of FMVSS 217.

EMC states that ''If the exception is not granted, the entertainers will suffer serious disruption to their tour schedules. Denial of the exemption will also lead to significant economic impacts due to the failure of the entertainers to be able to appear as scheduled. The substantial disruption is not merited by any insistence on the strict construction of any overly broad requirement that does not take the unique circumstances of Entertainer Coaches into account.''

**Request for Comments**

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public comment from all interested persons on EMC's application for an exemption from 49 CFR 393.62(a). All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice.

Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will continue to file relevant information in the public docket that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Issued on: April 24, 2015.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2015–10202 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–EX–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2015–0012]**

### Hours of Service of Drivers: Application for Exemption; American Trucking Associations, Inc.

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of application for exemption; request for comments.

**SUMMARY:** FMCSA announces that the American Trucking Associations, Inc. (ATA) has applied for an exemption from the Federal hours-of-service (HOS) regulations that prohibit commercial motor vehicle (CMV) drivers from driving a CMV if more than 8 consecutive hours have passed since the driver's last off-duty or sleeper-berth period of 30 minutes or more. ATA is requesting the exemption on behalf of all motor carriers that transport hazardous materials (HM) shipments requiring security plans under regulations of the Pipeline and Hazardous Materials Safety Administration (PHMSA). These plans normally require a driver to ''attend'' such cargo while the CMV is stopped, which would be an on-duty activity. This forces drivers to choose between FMCSA's off-duty rest break requirement and compliance with PHMSA's security plans, many of include an on-duty ''attendance'' requirement. ATA proposes that drivers transporting HM for motor carriers required to file security plans be allowed to count their on-duty ''attendance'' time for any HM cargo toward the required 30-minute rest break requirement, provided the drivers perform no other on-duty activity. The exemption would thus resemble Section 397.7, which requires drivers transporting certain explosives constantly to ''attend'' their load, while Section 395.1(q) allows them to count ''attendance'' time toward their rest break. FMCSA requests public comments on the request for exemption.

**DATES:** Comments must be received on or before June 1, 2015.

**ADDRESSES:** You may submit comments identified by Federal Docket Management System Number FMCSA–2015–0012 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

*Instructions:* All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the *Public Participation* heading below. Note that all comments received will be posted without change to *www.regulations.gov,* including any personal information provided. Please see the *Privacy Act* heading below.

*Docket:* For access to the docket to read background documents or comments received, go to *www.regulations.gov* at any time and in the box labeled ''SEARCH for'' enter FMCSA–2015–0012 and click on the tab labeled ''SEARCH.''

*Privacy Act:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

*Public Participation:* The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the ''help'' section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online.

**FOR FURTHER INFORMATION CONTACT:** Thomas L. Yager, Chief, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 614–942–6477; Email: *MCPSD@dot.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 2 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

**Request for Exemption**

Under 49 CFR 172.800–804, administered by PHMSA, carriers of certain security-sensitive HM must develop special plans that account for personnel, cargo, and en route security. Although not mandatory, ''constant attendance'' of the cargo is included by most carriers in their security plans.

''Constant attendance'' on a CMV is considered ''on duty time,'' as defined in 49 CFR 395.2. However, CMV drivers are subject to rest break requirements in Section 395.3(a)(3)(ii), which prohibit them from driving a CMV if more than 8 consecutive hours have passed since the driver's last off-duty or sleeper-berth period of 30 minutes or more. Drivers who are required by their carrier's HM security plan to maintain constant on-duty attendance on the CMV whenever stopped, cannot also comply with the off-duty rest break requirement of Section 395.3(a)(3)(ii).

Section 397.5 requires drivers transporting cargo classified as Division 1.1, 1.2, or 1.3 (explosive) materials to attend the cargo at all times. There is no regulatory conflict for these drivers, however, because Section 395.1(q) specifically allows them to count up to 30 minutes of their on-duty attendance time toward the rest break requirement, provided that they perform no other on-duty activities during that period.

ATA initially asked FMCSA ''to clarify that drivers can exercise constant attendance over a vehicle without having to remain on duty.'' After discussion with Agency officials, however, ATA agreed that its request should be treated as an exemption application. All correspondence on this issue has been placed in the docket listed at the beginning of this notice. The exemption request has been filed on behalf of all carriers whose drivers transport HM loads requiring placarding under 49 CFR part 172, subpart F, or select agents and toxins identified in Section 172.800(b)(13) that do not require placarding, and who have filed security plans requiring constant attendance of HM in accordance with Sections 172.800–804. The HM load being transported would not itself have to come under the provisions of Sections 172.800–804, because it would be too difficult for drivers and enforcement officials to determine at roadside whether Sections 182.800–804 applied to any individual load. Only drivers operating under the authority of carriers that have filed security plans under Sections 172.800–804 and who are transporting loads that require placarding or contain a select agent or toxin identified in Section 172.800(b)(13) would be eligible for this exemption. Drivers operating under this exemption could count up to 30 minutes of their on-duty attendance time toward a required rest break, provided that they perform no other on-duty activities during the rest-break period.

The driver would be required to annotate the record of duty status (''log book'') to show the time claimed as a rest break was on-duty time because he/she was required to follow the carrier's security plan, which in turn required ''attendance'' on an HM load.

It should be noted that a carrier or driver would have no reason to claim to be operating under this exemption unless it was necessary to do so to avoid a regulatory conflict. While under the exemption, if granted, the driver's rest-break time would be on-duty and count against the 60 or 70-hour on-duty limit. A rest break taken without using this exemption would be off-duty and not be included in the 60/70 hour limit.

ATA contends that allowing these drivers to count up to 30 minutes of their attendance time toward a required rest break, provided they perform no other on-duty activities during the break, would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation because the attendance duty would be unlikely to contribute to driver fatigue. ATA further contends that allowing these drivers to count up to 30 minutes of their attendance time toward a required rest break would provide security benefits superior to the current practices.

**Request for Comments**

In accordance with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA requests public comment on ATA's application for an exemption from the rest-break requirements of Section 395.3(a)(3)(ii). The Agency will consider all comments received by close of business on June 1, 2015.

Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. To the extent practicable, the Agency will consider comments received in the public docket after the closing date of the comment period.

Issued on: April 22, 2015.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2015–10200 Filed 4–30–15; 8:45 am]

BILLING CODE 4910–EX–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015–0045]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MOKULANI; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 1, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0045. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel MOKULANI is:

*Intended Commercial Use of Vessel:* Half day sailing tours, 6 pack.

*Geographic Region:* ''Hawaii.''

The complete application is given in DOT docket MARAD–2015–0045 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-

flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: April 24, 2015.

**Thomas M. Hudson,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–10291 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2015–0046]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel VANISHING GIRL; Invitation for Public Comments

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice.

**SUMMARY:** As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before June 1, 2015.

**ADDRESSES:** Comments should refer to docket number MARAD–2015–0046. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel VANISHING GIRL is:

*Intended Commercial Use of Vessel:* ''Recreational and instructional use in the Santa Barbara Channel area.''

*Geographic Region:* ''California.''

The complete application is given in DOT docket MARAD–2015–0046 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

**Privacy Act**

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: April 24, 2015.

**Thomas M. Hudson,**

*Acting Secretary, Maritime Administration.*

[FR Doc. 2015–10292 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. DOT–MARAD 2015 0047]**

### Request for Comments of a Previously Approved Information Collection: Effective U.S. Control (EUSC)/Parent Company

**AGENCY:** Maritime Administration (MARAD), Department of Transportation.

**ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on January 21, 2015 (80 FR 3005).

**DATES:** Comments must be submitted on or before June 1, 2015,

**FOR FURTHER INFORMATION CONTACT:** Russ Krause, 202–366–1031, Division of Sealift Operations and Emergency Response, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590.

**SUPPLEMENTARY INFORMATION:**

*Title:* Effective U.S. Control (EUSC)/Parent Company.

*OMB Control Number:* 2133–0511.

*Type of Request:* Renewal of a Previously Approved Information Collection.

*Abstract:* The Effective U.S. Control (EUSC) Parent Company collection consists of an inventory of foreign registered vessels owned by U.S. citizens. Specifically, the collection consists of responses from vessel owners verifying or correcting vessel ownership data and characteristics found in commercial publications. The information obtained could be vital in a national or international emergency, and is essential to the logistical support planning operations conducted by MARAD officials. The information is used in contingency planning and provides data related to potential sealift

capacity to support movement of fuel and military equipment to crisis zones.

*Affected Public:* U.S. citizens who own foreign-registered vessels.

*Estimated Number of Respondents:* 60.

*Estimated Number of Responses:* 60.

*Annual Estimated Total Annual Burden Hours:* 30.

**ADDRESSES:** Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.93.

Dated: April 27, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Maritime Secretary, Office of Chief Council.*

[FR Doc. 2015–10294 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. DOT–MARAD 2015 0048]**

### Request for Comments of a Previously Approved Information Collection: Regulations for Making Excess or Surplus Federal Property Available to the U.S. Merchant Marine Academy, State Maritime Academies and Non-Profit Maritime Training Facilities

**AGENCY:** Maritime Administration, Department of Transportation.

**ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on January 21, 2015 (**Federal Register** 3006, Vol. 80, No. 13).

**DATES:** Comments must be submitted on or before June 1, 2015.

**FOR FURTHER INFORMATION CONTACT:** Deveeda Midgette, (202) 366–2354, Office of Sealift Support, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590.

**SUPPLEMENTARY INFORMATION:**

*Title:* Regulations for Making Excess or Surplus Federal Property Available to the U.S. Merchant Marine Academy, State Maritime Academies and Non-Profit Maritime Training Facilities.

*OMB Control Number:* 2133–0504.

*Type of Request:* Renewal of a Previously Approved Information Collection.

*Abstract:* The Maritime Administration requires approved maritime training institutions seeking excess or surplus government property to provide a statement of need/justification prior to acquiring the property.

*Affected Public:* Maritime training institutions such as the U.S. Merchant Marine Academy, State Maritime Academies and non-profit maritime institutions.

*Estimated Number of Respondents:* 10.

*Estimated Number of Responses:* 40.

*Annual Estimated Total Annual Burden Hours:* 40.

**ADDRESSES:** Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.

Dated: April 27, 2015.

**Thomas M. Hudson, Jr.,**

*Acting Maritime Secretary, Office of Chief Counsel.*

[FR Doc. 2015–10293 Filed 4–30–15; 8:45 am]

**BILLING CODE 4910–81–P**

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[Docket No. MCF 21063]**

### National Express Transit Corporation—Acquisition of Control—Trans Express, Inc., and Rainbow Management Service Inc.

**AGENCY:** Surface Transportation Board.

**ACTION:** Notice Tentatively Approving and Authorizing Finance Transaction.

**SUMMARY:** National Express Transit Corporation (NETC or Applicant) has filed an application under 49 U.S.C. 14303 to acquire control of Trans Express Inc. (Trans Express) and Rainbow Management Service Inc. (Rainbow) (together, Acquisition Carriers). The Board is tentatively approving and authorizing the transaction and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules at 49 CFR 1182.5 and 1182.8.

**DATES:** Comments must be filed by June 15, 2015. Applicant may file a reply by June 30, 2015. If no comments are filed by June 15, 2015, this notice shall be effective on June 16, 2015.

**ADDRESSES:** Send an original and 10 copies of any comments referring to Docket No. MCF 21063 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send one copy of comments to Applicant's representative: Andrew K. Light, Scopelitis, Garvin, Light, Hanson & Feary, P.C., Suite 1500, 10 W. Market Street, Indianapolis, IN 46204.

**FOR FURTHER INFORMATION CONTACT:** Amy Ziehm, (202) 245–0391. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:** NETC is an intrastate motor carrier of passengers incorporated under the laws of Delaware. NETC, which does not have interstate authority from the Federal Motor Carrier Safety Administration (FMCSA), is held directly by National Express LLC (NELLC), a Delaware limited liability company. NELLC, in turn, is indirectly controlled by a British corporation, National Express Group, PLC (Express Group). Express Group

also indirectly controls the following interstate and intrastate motor carriers of passengers: A&E Transport Services, Inc. (MC–319820); Beck Bus Transportation Corp. (Beck) (MC–43528); Carrier Management Inc. (CMI); Community Transportation Inc. (Community); Durham School Services, L.P. (Durham) (MC–163066); MV Student Transportation Inc. (MV) (MC–148934); National Express Transit Services Corporation (NETSC), Petermann Ltd. (LTD) (MC–364668); Petermann Northeast LLC (Northeast) (MC–723926); Petermann Northwest LLC (Northwest); Petermann Southwest LLC (Southwest) (MC–644996); Petermann STSA, LLC (STSA) (MC–749360); Vogel Bus Company Inc. (MC–274520); and Stock Transportation Ltd. Of these companies, all but Community and NETSC provide school bus transportation services.[1] Community provides intrastate transit services in Pennsylvania and NETSC provides intrastate transit services in the areas of Westmoreland, Pa., Arlington, Va., Greensboro, N.C., Vallejo, Cal., and Yuma, Ariz. In addition to school bus services, Beck, CMI, Durham, MV, LTD, Northeast, Southwest, and STSA also provide charter passenger services to the public.

The Acquisition Carriers, both motor carriers of passengers, are New York corporations. Trans Express holds interstate authority from FMCSA (MC–187819) and provides point-to-point intrastate passenger service between the Boroughs of Brooklyn and Manhattan in New York, utilizing 40 vehicles consisting of 28 owned buses and 12 trip-leased motor coaches. Rainbow also holds a FMCSA license (MC–490015) and provides interstate and intrastate charter and special party passenger transportation services in New York City and the State of New York and also holds intrastate authority from the New York Department of Transportation. Rainbow utilizes 16 vehicles consisting of one motor coach and 15 mini-buses. Mary Rubino and Christina Rubino hold all of the issued and outstanding stock of the Acquisition Carriers.

Applicant states that the proposed transaction would place the Acquisition Carriers under the control of NETC. The proposed transaction contemplates that NETC would assume 100 percent control of the Acquisition Carriers through stock ownership. Applicant states that after the transaction, the Acquisition Carriers would continue to provide services under the same names, but would be operated within the NETC corporate family. Applicant asserts that NETC is experienced in the passenger service markets already served by NETC and some of its affiliated carriers.

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Applicant has submitted information, as required by 49 CFR 1182.2, including the information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that NETC's aggregate gross operating revenues exceeded $2 million for the preceding twelve-month period, *see* 49 U.S.C. 14303(g).

Applicant submits that the proposed transaction would not have a material, detrimental impact on the adequacy of transportation services to the public, but would improve services to the public. Applicant does not intend to change the operations of the Acquisition Carriers and would operate them within the NETC corporate family, which, it states, would enhance the overall viability of the carriers within the corporate family. Applicant anticipates that the proposed transaction would result in operating efficiencies and cost savings derived from economies of scale, which would help ensure adequate service to the public. With respect to fixed charges, Applicant states that there are no fixed charges associated with the proposed transaction. Applicant states that the proposed transaction would not have a substantial impact on employees, as NETC does not anticipate a measurable reduction in force or compensation levels. However, according to Applicant, staffing redundancies could potentially result in limited downsizing of back-office and/or managerial level personnel.

Applicant further asserts that the proposed transaction would not adversely affect competition or the public interest. Applicant claims that the Acquisition Carriers are relatively small carriers in the overall markets in which they compete—intrastate point-to-point passenger service, interstate and intrastate charter passenger service, and special party passenger service. Applicant further states that the affiliated carriers that operate school buses occupy a limited portion of the charter business because the equipment is not as comfortable as motor coaches and the scheduling demands imposed by school bus operations constrains services that could be offered. Applicant asserts that the charter operations offered by NETC and its affiliates are geographically dispersed and there is little overlap in service areas among NETC, its affiliates, and the Acquisition Carriers. Applicant notes the Board's findings in other cases that ease of entry into the motor carrier market results in competition in the motor carrier industry as well as competition from other modes of transportation.

On the basis of the application, the Board finds that the proposed acquisition of control is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV*''.

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

*It is ordered:*

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective June 16, 2015, unless opposing comments are filed by June 15, 2015.

4. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: April 24, 2015.

By the Board, Acting Chairman Miller and Vice Chairman Begeman.

**Kenyatta Clay,**

*Clearance Clerk.*

[FR Doc. 2015–10209 Filed 4–30–15; 8:45 am]

**BILLING CODE 4915–01–P**

[1] The application does not describe the operations of Northwest.

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

### Applications of Eastern Air Lines Group, Inc. for Certificate Authority

**AGENCY:** Department of Transportation.

**ACTION:** Notice of Order to Show Cause (Order 2015–4–16); Dockets DOT–OST–2014–0012 and DOT–OST–2014–0013.

**SUMMARY:** The Department of Transportation is directing all interested persons to show cause why it should not issue orders finding Eastern Air Lines Group, Inc. fit, willing, and able, and awarding it certificates of public convenience and necessity authorizing it to engage in interstate and foreign charter air transportation of persons, property, and mail.

**DATES:** Persons wishing to file objections should do so no later than April 27, 2015.

**ADDRESSES:** Objections and answers to objections should be filed in Dockets DOT–OST–2014–0012 and DOT–OST–2014–0013 and addressed to the Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC and should be served upon the parties listed in Attachment A to the order.

**FOR FURTHER INFORMATION CONTACT:** Catherine O'Toole, Air Carrier Fitness Division, (X–56, Office W86–469), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–9721.

Dated: April 20, 2015.

**Brandon M. Belford,**

*Deputy Assistant Secretary for Aviation and International Affairs.*

[FR Doc. 2015–09683 Filed 4–30–15; 8:45 am]

BILLING CODE P

# FEDERAL REGISTER

Vol. 80 Friday,

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Part II

## Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412

Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2015 (FY 2016); Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 412**

**[CMS–1627–P]**

**RIN 0938–AS47**

# Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2015 (FY 2016)

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would update the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs) (which are freestanding IPFs and psychiatric units of an acute care hospital or critical access hospital). These changes would be applicable to IPF discharges occurring during the fiscal year (FY) beginning October 1, 2015 through September 30, 2016 (FY 2016). This proposed rule also proposes: A new IPF-specific market basket; to update the IPF labor-related share; a transition to new Core Based Statistical Area (CBSA) designations in the FY 2016 IPF Prospective Payment System (PPS) wage index; to phase out the rural adjustment for IPF providers whose status changes from rural to urban as a result of the proposed wage index CBSA changes; and new quality measures and reporting requirements under the IPF quality reporting program. This proposed rule also reminds IPFs of the October 1, 2015 implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM), and updates providers on the status of IPF PPS refinements.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 23, 2015.

**ADDRESSES:** In commenting, please refer to file code CMS–1627–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–1627–P, P.O. Box 8010, Baltimore, MD 21244–1850.

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–1627–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, call telephone number (410) 786–4492 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:**

Katherine Lucas or Jana Lindquist, (410) 786–7723, for general information.

Hudson Osgood, (410) 786–7897 or Bridget Dickensheets, (410) 786–8670, for information regarding the market basket and labor-related share.

Theresa Bean, (410) 786–2287, for information regarding the regulatory impact analysis.

Rebecca Kliman, (410) 786–9723, or Jeffrey Buck, (410) 786–0407, for information regarding the inpatient psychiatric facility quality reporting program.

**SUPPLEMENTARY INFORMATION:**

## Availability of Certain Tables Exclusively Through the Internet on the CMS Web Site

In the past, tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas were published in the **Federal Register** as an Addendum to the annual PPS rulemaking (that is, the PPS proposed and final rules or, when applicable, the current update notice). However, beginning in FY 2015, these wage index tables are no longer published in the **Federal Register**. Instead, these tables will be available exclusively through the Internet. The wage index tables for this proposed rule are available exclusively through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/Wage Index.html*.

To assist readers in referencing sections contained in this document, we are providing the following table of contents.

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## Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

ADC Average Daily Census
AHA American Hospital Association
AHE Average Hourly Earning
BBRA Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BEA Bureau of Economic Analysis
BLS Bureau of Labor Statistics
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CCR Cost-to-Charge Ratio
CPI Consumer Price Index
CPI–U Consumer Price Index for all Urban Consumers
DRGs Diagnosis-Related Groups
ECI Employment Cost Index
ESRD End State Renal Disease
FR Federal Register
FTE Full-time equivalent
FY Federal Fiscal Year (October 1 through September 30)
GDP Gross Domestic Product
GME Graduate Medical Education
HHA Home Health Agency
HBIPS Hospital Based Inpatient Psychiatric Services
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, 10th Revision, Procedure Coding System
IGI IHS Global Insight, Inc.
I–O Input—Output
IPFs Inpatient Psychiatric Facilities
IPFQR Inpatient Psychiatric Facilities Quality Reporting
IRFs Inpatient Rehabilitation Facilities
LOS Length of Stay
LTCHs Long-Term Care Hospitals
MAC Medicare Administrative Contractor
MedPAR Medicare Provider Analysis and Review File
MFP Multifactor Productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA Metropolitan Statistical Area
NAICS North American Industry Classification System
NQF National Quality Forum
OES Occupational Employment Statistics
OMB Office of Management and Budget
OPPS Outpatient Prospective Payment System
PLI Professional Liability Insurance
PPI Producer Price Index
PPS Prospective Payment System
RPL Rehabilitation, Psychiatric, and Long-Term Care
RY Rate Year (July 1 through June 30)
SCHIP State Children's Health Insurance Program
SNF Skilled Nursing Facility
SOC Standard Occupational Classification
TEFRA Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248)

## I. Executive Summary

### *A. Purpose*

This proposed rule would update the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs) for discharges occurring during the fiscal year (FY) beginning October 1, 2015 through September 30, 2016. For the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, it also would change the measures collected under the program and modify reporting requirements for all program measures.

### *B. Summary of the Major Provisions*

In this proposed rule, we would update the IPF Prospective Payment

System (PPS), as specified in 42 CFR 412.428. The updates include the following:

- Effective for FY 2016 IPF PPS update, we are proposing to adopt a FY 2012-based IPF-specific market basket. We propose to adjust the FY 2012-based IPF market basket update (currently estimated to be 2.7 percent) by a reduction for economy-wide productivity (currently estimated to be 0.6 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act), and further reduced by 0.2 percentage point as required by section 1886(s)(2)(A)(ii) of the Act, resulting in an estimated market basket update of 1.9 percent.
- We propose to update the IPF per diem rate from $728.31 to $745.19. Providers that failed to report quality data for FY 2016 payment would receive a proposed FY 2016 per diem rate of $730.56.
- We propose to update the electroconvulsive therapy (ECT) payment from $313.55 to $320.82. Providers that failed to report quality data for FY 2016 payment would receive a proposed FY 2016 ECT rate of $314.52.
- We propose to adopt new Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) delineations for the FY 2016 IPF PPS wage index and future IPF PPS wage indices. We propose to implement these CBSA changes using a 1-year transition with a blended wage index for all providers, consisting of a blend of fifty percent of the FY 2016 IPF wage index using the current OMB delineations and fifty percent of the FY 2016 IPF wage index using the revised OMB delineations.
- We propose to phase out the rural adjustment for the 37 rural IPFs that would be re-designated as urban IPFs due to the OMB CBSA changes. Specifically, we propose to phase out the 17 percent rural adjustment for these 37 providers over 3 years (2-thirds of the adjustment given in FY 2016, one-third of the adjustment given in FY 2017, and no rural adjustment thereafter).
- We propose to use the updated Labor Related Share of 74.9 percent and CBSA rural and urban wage indices for FY 2016, and establish a wage index budget-neutrality adjustment of 1.0041.
- We propose to update the fixed dollar loss threshold amount from $8,755 to $9,825 in order to maintain outlier payments that are 2 percent of total IPF PPS payments.
- We propose that the national urban and rural cost-to-charge ratio (CCR) ceilings for FY 2016 would be 1.6881 and 1.9041, respectively, and the national median CCR would be 0.4675 for urban IPFs and 0.6210 for rural IPFs. The national median CCR is applied to new IPFs that have not yet submitted their first Medicare cost report, to IPFs for which the CCR calculation data are inaccurate or incomplete, or to IPFs whose overall CCR exceeds 3 standard deviations above the national geometric mean. These amounts are used in the outlier calculation to determine if an IPF's CCR is statistically accurate and for new providers without an established CCR.
- We note that IPF PPS patient-level and facility-level adjustments, other than those mentioned above, would remain the same as in FY 2015.

In addition:

- We remind providers that International Classification of Diseases, 10th Revision, Clinical Modification/Procedure Coding System (ICD–10–CM/PCS) will be implemented on October 1, 2015.
- As we continue our analysis for future IPF PPS refinements, we find, from preliminary analysis of 2012 to 2013 data, that over 20 percent of IPF stays reported no ancillary costs, such as laboratory and drug costs, in their cost reports, or laboratory or drug charges on their claims. Because we expect that most patients requiring hospitalization for active psychiatric treatment would need drugs and laboratory services, we remind providers that the IPF per diem payment rate includes the cost of all ancillary services, including drugs and laboratory services. CMS pays only the inpatient psychiatric facility for services furnished to a Medicare beneficiary who is an inpatient of that inpatient psychiatric facility, except for certain professional services, and payments are considered to be payments in full for all inpatient hospital services provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

For the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, we are making several proposals related to measures and several proposals related to data submission for the IPFQR Program measures. We are proposing to adopt five new measures beginning with the fiscal year (FY) 2018 payment determination:

- TOB–3—Tobacco Use Treatment Provided or Offered at Discharge and the subset measure TOB–3a Tobacco Use Treatment at Discharge (National Quality Forum (NQF) #1656);
- SUB–2—Alcohol Use Brief Intervention Provided or Offered and the subset measure SUB–2a (NQF #1663);
- Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF) #0647);
- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648); and
- Screening for Metabolic Disorders.

If Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) is adopted, we are proposing to remove Hospital Based Inpatient Psychiatric Services (HBIPS)–6 Post-Discharge Continuing Care Plan (NQF #0557). Likewise, if Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) is adopted, we are proposing to remove HBIPS–7 Post-Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge (NQF #0558). We are also proposing to remove one measure, HBIPS–4 Patients Discharged on Multiple Antipsychotic Medications, beginning with the FY 2017 payment determination.

We are also making several proposals regarding how facilities should report data for IPFQR Program measures:

- We are proposing to require that measures be reported as a single yearly count rather than by quarter and age beginning with the FY 2017 payment determination;
- We are proposing to require that aggregate population counts be reported as a single yearly number rather than by quarter beginning with the FY 2017 payment determination; and
- We are proposing to allow uniform sampling for certain measures beginning with the FY 2018 payment determination.

*C. Summary of Impacts*

| Provision description | Total transfers |
|---|---|
| FY 2016 IPF PPS payment rate update | The overall economic impact of this proposed rule is an estimated $80 million in increased payments to IPFs during FY 2016. |
| **Provision description** | **Costs** |
| New quality reporting program requirements | The total costs beginning in FY 2016 for IPFs as a result of the proposed new quality reporting requirements are estimated to be $6.31 million. |

## II. Background

### *A. Overview of the Legislative Requirements for the IPF PPS*

Section 124 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department Health and Human Services (the Secretary) develop a per diem PPS for inpatient hospital services furnished in psychiatric hospitals and psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and psychiatric units.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to distinct part psychiatric units of critical access hospitals (CAHs).

Section 3401(f) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to as ''the Affordable Care Act'') added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled ''Reference to Establishment and Implementation of System'' refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the Rate Year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. For the RY beginning in 2015 (that is, FY 2016), the current estimate of the productivity adjustment would be equal to 0.6 percentage point, which we are proposing in this FY 2016 proposed rule.

Section 1886(s)(2)(A)(ii) of the Act requires the application of an ''other adjustment'' that reduces any update to an IPF PPS base rate by percentages specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. For the RY beginning in 2015 (that is, FY 2016), section 1886(s)(3)(D) of the Act requires the reduction to be 0.2 percentage point. We are proposing that reduction in this FY 2016 IPF PPS proposed rule.

Section 1886(s)(4) of the Act requires the establishment of a quality data reporting program for the IPF PPS beginning in RY 2014.

To implement and periodically update these provisions, we have published various proposed and final rules in the **Federal Register**. For more information regarding these rules, see the CMS Web site at *http://www.cms.hhs.gov/InpatientPsychFacilPPS/*.

### *B. Overview of the IPF PPS*

The November 2004 IPF PPS final rule (69 FR 66922) established the IPF PPS, as required by section 124 of the BBRA and codified at subpart N of part 412 of the Medicare regulations. The November 2004 IPF PPS final rule set forth the per diem Federal rates for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006), and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget-neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described above and certain patient- and facility-level payment adjustments that were found in the regression analysis to be associated with statistically significant per diem cost differences.

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, comorbidities, and variable per diem adjustments to reflect higher per diem costs in the early days of an IPF stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for: Outlier cases; interrupted stays; and a per treatment adjustment for patients who undergo electroconvulsive therapy (ECT). During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended in 2008, these payments are no longer available.

A complete discussion of the regression analysis that established the IPF PPS adjustment factors appears in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology. Therefore, in the November 2004 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

In RY 2012, we proposed and finalized switching the IPF PPS payment rate update from a rate year that begins on July 1 and ends on June 30 to one that coincides with the Federal fiscal year that begins October 1 and ends on September 30. In order to

transition from one timeframe to another, the RY 2012 IPF PPS covered a 15-month period from July 1, 2011 through September 30, 2012. Therefore, the update cycle for FY 2016 will be October 1, 2015 through September 30, 2016. For further discussion of the 15-month market basket update for RY 2012 and changing the payment rate update period to coincide with a FY period, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and the RY 2012 IPF PPS final rule (76 FR 26432).

*C. Annual Requirements for Updating the IPF PPS*

In November 2004, we implemented the IPF PPS in a final rule that appeared in the November 15, 2004 **Federal Register** (69 FR 66922). In developing the IPF PPS, to ensure that the IPF PPS is able to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In that final rule, we explained that we believe it is important to delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. Therefore, we indicated that we did not intend to update the regression analysis and the patient- and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (71 FR 27041). We have begun the necessary analysis to make refinements to the IPF PPS using more current data to set the adjustment factors; however, we are not proposing any refinements in this proposed rule. Rather, as explained in section IV.B. of this proposed rule, we expect that in future rulemaking we will be ready to propose potential refinements.

In the May 6, 2011 IPF PPS final rule (76 FR 26432), we changed the payment rate update period to a RY that coincides with a FY update. Therefore, update notices are now published in the **Federal Register** in the summer to be effective on October 1. When proposing changes in IPF payment policy, a proposed rule would be issued in the spring and the final rule in the summer in order to be effective on October 1. For further discussion on changing the IPF PPS payment rate update period to a RY that coincides with a FY, see the IPF PPS final rule published in the **Federal Register** on May 6, 2011 (76 FR 26434 through 26435). For a detailed list of updates to the IPF PPS, see 42 CFR 412.428.

Our most recent IPF PPS annual update occurred in an August 6, 2014, **Federal Register** final rule (79 FR 45938) (hereinafter referred to as the August 2014 IPF PPS final rule) that set forth updates to the IPF PPS payment rates for FY 2015. That rule updated the IPF PPS per diem payment rates that were published in the August 2013 IPF PPS notice (78 FR 46734) in accordance with our established policies.

**III. Provisions of the Proposed Rule**

*A. Proposed Market Basket for the IPF PPS*

1. Background

The input price index that was used to develop the IPF PPS was the Excluded Hospital with Capital market basket. This market basket was based on 1997 Medicare cost reports for Medicare participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although ''market basket'' technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term ''market basket,'' as used in this document, refers to an input price index.

Beginning with the May 2006 IPF PPS final rule (71 FR 27046 through 27054), IPF PPS payments were updated using a 2002-based RPL market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. Cancer and children's hospitals were excluded from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act and not through a PPS. Also, the 2002 cost structures for cancer and children's hospitals are noticeably different than the cost structures of freestanding IRFs, freestanding IPFs, and LTCHs. See the May 2006 IPF PPS final rule (71 FR 27046 through 27054) for a complete discussion of the 2002-based RPL market basket.

In the May 1, 2009 IPF PPS notice (74 FR 20376), we expressed our interest in exploring the possibility of creating a stand-alone IPF market basket that reflects the cost structures of only IPF providers. One available option was to combine the Medicare cost report data from freestanding IPF providers with Medicare cost report data from hospital-based IPF providers. We indicated that an examination of the Medicare cost report data comparing freestanding IPFs and hospital-based IPFs showed differences between cost levels and cost structures. At that time, we were unable to fully understand these differences even after reviewing explanatory variables such as geographic variation, case mix (including DRG, comorbidity, and age), urban or rural status, teaching status, and presence of a qualifying emergency department. As a result, we continued to research ways to reconcile the differences and solicited public comment for additional information that might help us to better understand the reasons for the variations in costs and cost structures, as indicated by the Medicare cost report data (74 FR 20376). We summarized the public comments we received and our responses in the April 2010 IPF PPS notice (75 FR 23111 through 23113). Despite receiving comments from the public on this issue, we were still unable to sufficiently reconcile the observed differences in costs and cost structures between hospital-based and freestanding IPFs, and, therefore, we did not believe it to be appropriate at that time to incorporate data from hospital-based IPFs with those of freestanding IPFs to create a stand-alone IPF market basket.

Beginning with the RY 2012 IPF PPS final rule (76 FR 26432), IPF PPS payments were updated using a 2008-based RPL market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. The major changes for RY 2012 included: Updating the base year from FY 2002 to FY 2008; using a more specific composite chemical price proxy; breaking the professional fees cost category into 2 separate categories (Labor-related and Nonlabor-related); and adding 2 additional cost categories (Administrative and Facilities Support Services and Financial Services), which were previously included in the residual All Other Services cost categories. The RY 2012 IPF PPS proposed rule (76 FR 4998) and RY 2012 final rule (76 FR 26432) contain a complete discussion of the development of the 2008-based RPL market basket.

For FY 2016, we are proposing to create a 2012-based IPF market basket, using Medicare cost report data for both

freestanding and hospital-based IPFs. In the following discussion, we provide an overview of the proposed market basket and describe the methodologies used to determine the operating and capital portions of the proposed 2012-based IPF market basket.

2. Overview of the Proposed 2012-Based IPF Market Basket

The proposed 2012-based IPF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in 3 steps. First, a base period is selected (in this proposed rule, the base period is FY 2012) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories with the proportion of total costs that each category represents being calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish IPF services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an IPF hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the IPF, but would not be factored into the price change measured by a fixed-weight IPF market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that IPFs purchase (facility inputs) to furnish inpatient care between base periods.

3. Creating an IPF-Specific Market Basket

As discussed in section III.A.1, over the last several years we have been exploring the possibility of creating a stand-alone, or IPF-specific, market basket that reflects the cost structures of only IPF providers. The major cost weights for the 2008-based RPL market basket were calculated using Medicare cost report data for freestanding facilities only. We used freestanding facilities due to concerns regarding our ability to incorporate Medicare cost report data for hospital-based providers. In the FY 2015 IPF PPS final rule (79 FR 45941), we presented several of these concerns (as stated below) but explained that we would continue to research the possibility of creating an IPF-specific market basket to update IPF PPS payments.

Since the FY 2015 IPF PPS final rule, we have performed additional research on the Medicare cost report data available for hospital-based IPFs and evaluated these concerns. We subsequently concluded from this research that Medicare cost report data for both hospital-based IPFs and freestanding IPFs can be used to calculate the major market basket cost weights for a stand-alone IPF market basket. We have developed a detailed methodology to derive market basket cost weights that are representative of the universe of IPF providers. We believe the use of this proposed IPF market basket is a technical improvement over the RPL market basket that is currently used to update IPF PPS payments. As a result, in this FY 2016 IPF PPS proposed rule, we are proposing a 2012-based IPF market basket that reflects data for both freestanding and hospital-based IPFs. Below we discuss our prior concerns and provide reasons for why we now feel it is appropriate to create a stand-alone IPF market basket using Medicare cost report data for both hospital-based and freestanding IPFs.

One concern we discussed in the FY 2015 IPF PPS final rule (79 FR 45941) about using the hospital-based IPF Medicare cost report data was the cost level differences for hospital-based IPFs relative to freestanding IPFs were not readily explained by the specific characteristics of the individual providers and the patients that they serve (for example, characteristics related to case mix, urban/rural status, teaching status, or presence of a qualified emergency department). To address this concern, we used regression analysis to evaluate the effect of including hospital-based IPF Medicare cost report data in the calculation of cost distributions. A more detailed description of these regression models can be found in the FY 2015 IPF final rule (79 FR 45941). Based on this analysis, we concluded that the inclusion of those IPF providers with unexplained variability in costs did not significantly impact the cost weights and, therefore, should not be a major cause of concern.

Another concern regarding the incorporation of hospital-based IPF data into the calculation of the market basket cost weights was the complexity of the Medicare cost report data for these providers. The freestanding IPFs independently submit a Medicare cost report for their facilities, making it relatively straightforward to obtain the cost categories necessary to determine the major market basket cost weights. However, Medicare cost report data submitted for a hospital-based IPF are embedded in the Medicare cost report submitted for the entire hospital facility in which the IPF is located. In order to use Medicare cost report data from these providers, we needed to determine the appropriate adjustments to apply to the data to ensure that the cost weights we obtained would represent only the hospital-based IPF (not the hospital as a whole). Over the past year, we worked to develop detailed methodologies to calculate the major cost weights for both freestanding and hospital-based IPFs. We believe that our proposed methodologies and the resulting cost weights, described in section III.A.3.a.i below, are reasonable and appropriate. We welcome public comments on these proposals.

We also evaluated the differences in cost weights for hospital-based and freestanding IPFs and found the most significant differences occurred for salaries and pharmaceutical costs. Specifically, the hospital-based IPF salary cost weights tend to be lower than those of freestanding IPFs while hospital-based IPF pharmaceutical cost weights tend to be higher than those of freestanding IPFs. Our proposed methodology for deriving costs for each of these categories can be found in section III.A.3.a.i below. We will continue to research and monitor these

cost shares to ensure that the differences are explainable.

In summary, our research over the past year allowed us to evaluate the appropriateness of including hospital-based IPF data in the calculation of the major cost weights for an IPF market basket. We believe that the proposed methodologies for deriving the cost weights give us the ability to create a stand-alone IPF market basket that reflects the cost structure of the universe of IPF providers. Therefore, we believe that the use of this proposed 2012-based IPF market basket to update IPF PPS payments is an improvement over the current 2008-based RPL market basket.

a. Development of Cost Categories and Weights

i. Medicare Cost Reports

The proposed 2012-based IPF market basket consists of seven major cost categories derived from the FY 2012 Medicare cost reports (CMS Form 2552–10) for freestanding and hospital-based IPFs, including Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Capital, and a residual. The residual reflects all remaining costs that are not captured in the other six cost categories. The FY 2012 cost reports include providers whose cost report begin date is on or between October 1, 2011, and September 30, 2012. We choose to use FY 2012 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for IPFs at the time of rulemaking.

Prior Medicare cost report data used to develop the RPL market basket showed large differences between some providers' Medicare length of stay (LOS) and total facility LOS. Since our goal is to measure cost weights that are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries, we limited our selection of Medicare cost reports used in the RPL market basket to those facilities that had a Medicare LOS that was within a comparable range of their total facility average LOS. For the 2008-based RPL market basket, we used those IPF Medicare cost reports whose average Medicare LOS was within 30 percent of the average facility LOS if the facility LOS was greater than or equal to 15 days. For those IPFs whose average facility LOS was less than 15 days, the Medicare LOS had to be within 50 percent of the average facility LOS. When applying the LOS trim to derive the 2008-based RPL market basket, we found that those providers that were excluded (of which seventy percent were IPFs) had an average facility LOS (40 days) that was 2 times larger than the Medicare LOS (20 days).

To create the proposed 2012-based IPF market basket, we reevaluated the LOS trim based on FY 2012 Medicare cost report data and the inclusion of hospital-based providers. Based on our analysis of the data, we are proposing to apply a less restrictive LOS trim to derive the 2012-based IPF market basket than was applied to derive the RPL market basket. For freestanding IPFs, we propose to define the Medicare and facility LOS as those reported on line 14 of Worksheet S–3, Part I (consistent with the RPL market basket method). For hospital-based IPFs, we are proposing to use line 16 of Worksheet S–3, Part I to determine the Medicare and facility LOS. To derive the proposed 2012-based IPF market basket, for those IPFs with an average facility LOS of greater than or equal to 15 days, we are proposing to include IPFs where the Medicare LOS is within 50 percent (higher or lower) of the average facility LOS. For those IPFs whose average facility LOS is less than 15 days, we are proposing to include IPFs where the Medicare LOS is within 95 percent (higher or lower) of the facility LOS.

This less restrictive trim increases the number of IPFs included in the derivation of the market basket, particularly for those providers where the Medicare LOS and facility LOS is within 5 days. Applying the proposed trim results in IPF Medicare cost reports with an average Medicare LOS of 12 days, average facility LOS of 10 days, and Medicare utilization (as measured by Medicare inpatient IPF days as a percentage of total facility days) of 30 percent. If we were to apply the same trim as was applied for the 2008-based RPL market basket, it would result in IPF Medicare cost reports with an average Medicare LOS of 12 days, average facility LOS of 9 days, and Medicare utilization of 31 percent. Those providers that were excluded from the proposed 2012-based IPF market basket have an average Medicare LOS of 22 days, average facility LOS of 49 days, and a Medicare utilization of 5 percent. Of those Medicare cost reports excluded from the proposed 2012-based IPF market basket, about 70 percent of these were freestanding providers whereas freestanding providers represent about 30 percent of all IPFs. We believe the proposed trim is a technical improvement as data from more IPFs is used while still being reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries.

We applied this LOS trim to first obtain a set of cost reports for facilities that have a Medicare LOS within a comparable range of their total facility LOS. Using the resulting set of FY 2012 Medicare cost reports for freestanding IPFs and hospital-based IPFs, we are proposing to calculate costs for the six major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital).

Similar to the 2008-based RPL market basket major cost weights, the proposed 2012-based IPF market basket cost weights reflect Medicare allowable costs (routine, ancillary and capital costs) that are eligible for inclusion under the IPF PPS payments. We define Medicare allowable costs for freestanding facilities as cost centers (CMS Form 2552–10): 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93. We define Medicare allowable costs for hospital-based facilities as cost centers (CMS Form 2552–10): 40, 50 through 76 (excluding 52 and 75), 90 through 91, and 93. For freestanding IPFs, total Medicare allowable costs are equal to the total costs as reported on Worksheet B, part I, column 26. For hospital-based IPFs, total Medicare allowable costs are equal to total costs for the IPF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 40) and a portion of total ancillary costs. We calculate the portion of ancillary costs attributable to the hospital-based IPF for a given ancillary cost center by multiplying total facility ancillary costs for the specific cost center (as reported on Worksheet B, Part I, column 26) by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for IPF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant PPS (that is, IPPS, IRF, IPF and Skilled Nursing Facility (SNF))).

Below we provide a description of the proposed methodologies used to derive costs for the six major cost categories.

Wages and Salaries Costs

For freestanding IPFs, Wages and Salaries costs are derived as the sum of routine inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, column 1. Since overhead salary costs are attributable to the entire IPF, we only include the proportion attributable to the Medicare allowable cost centers. We

estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable salaries to total salaries (Worksheet A, column 1, line 200) times total overhead salaries. A similar methodology was used to derive Wages and Salaries costs in the 2008-based RPL market basket.

For hospital-based IPFs, Wages and Salaries costs are derived as the sum of inpatient unit wages and salaries (Worksheet A, column 1, line 40) and a portion of salary costs attributable to total facility ancillary and overhead cost centers as these cost centers are shared with the entire facility. We calculate the portion of ancillary salaries attributable to the hospital-based IPF for a given ancillary cost center by multiplying total facility ancillary salary costs for the specific cost center (as reported on Worksheet A, column 1) by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for IPF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant PPS units (that is, IPPS, IRF, IPF and SNF)). For example, if hospital-based IPF Medicare laboratory costs represent 10 percent of the total Medicare laboratory costs for the entire facility, then 10 percent of total facility laboratory salaries (as reported in Worksheet A, column 1, line 60) would be attributable to the hospital-based IPF. We believe it is appropriate to use only a portion of the ancillary costs in the market basket cost weight calculations since the hospital-based IPF only utilizes a portion of the facility's ancillary services. We believe the ratio of reported IPF Medicare costs to reported total Medicare costs provides a reasonable estimate of the ancillary services utilized, and costs incurred, by the hospital-based IPF.

We calculate the portion of overhead salary costs attributable to hospital-based IPFs by multiplying the total overhead costs attributable to the hospital-based IPF (sum of columns 4 through18 on Worksheet B, part I, line 40) by the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4 through18) to total facility overhead costs (as reported on Worksheet A, column 7, lines 4 through18). This methodology assumes the proportion of total costs related to salaries for the overhead cost centers is similar for all inpatient units (that is, acute inpatient or inpatient psychiatric). Since the 2008-based RPL market basket did not include hospital-based providers, this proposed methodology cannot be compared to the derivation of Wages and Salaries costs in the 2008-based RPL market basket.

Employee Benefits Costs

Effective with our implementation of CMS Form 2552–10, CMS began collecting Employee Benefits and Contract Labor data on Worksheet S–3, Part V. Previously, with CMS Form 2540–96, Employee Benefits and Contract Labor data were reported on Worksheet S–3, part II, which was applicable to only IPPS providers and, therefore, these data were not available for the derivation of the RPL market basket. Due to the lack of such data, the Employee Benefits cost weight for the 2008-based RPL market basket was derived by multiplying the 2008-based RPL market basket Wages and Salaries cost weight by the ratio of the IPPS hospital market basket Employee Benefits cost weight to the IPPS hospital market basket Wages and Salaries cost weight. Similarly, the Contract Labor cost weight for the 2008-based RPL market basket was derived by multiplying the 2008-based RPL market basket Wages and Salaries cost weight by the ratio of the IPPS hospital market basket Contract Labor cost weight to the IPPS hospital market basket Wages and Salaries cost weight.

For FY 2012 Medicare cost report data, while there were providers that did report data on Worksheet S–3, part V, many providers did not complete this worksheet. However, we believe we had a large enough sample to enable us to produce reasonable Employee Benefits cost weights. We continue to encourage all providers to report these data on the Medicare cost report.

For freestanding IPFs, Employee Benefits costs are equal to the data reported on Worksheet S–3, Part V, line 2, column 2.

For hospital-based IPFs, we calculate total benefits as the sum of benefit costs reported on Worksheet S–3 Part V, line 3, column 2, and a portion of ancillary benefits and overhead benefits for the total facility. Ancillary benefits attributable to the hospital-based IPF are calculated by multiplying ancillary salaries for the hospital-based IPF as determined in the derivation of Wages and Salaries for the hospital-based IPF by the ratio of total facility benefits to total facility salaries. Similarly, overhead benefits attributable to the hospital-based IPF are calculated by multiplying overhead salaries for the hospital-based IPF as determined in the derivation of Wages and Salaries for the hospital-based IPF by the ratio of total facility benefits to total facility salaries.

Contract Labor Costs

Similar to the RPL and IPPS market baskets, Contract Labor costs are primarily associated with direct patient care services. Contract labor costs for other services such as accounting, billing, and legal are calculated separately using other government data sources as described in section III.A.3.a.ii. As discussed above in the Employee Benefits section, we now have data reported on Worksheet S–3, Part V that we can use to derive the Contract Labor cost weight for the 2012-based IPF market basket. For freestanding IPFs, Contract Labor costs are based on data reported on Worksheet S–3, part V, column 1, line 2 and for hospital-based IPFs Contract Labor costs are based on line 3 of this same worksheet. As previously noted, for FY 2012 Medicare cost report data, while there were providers that did report data on Worksheet S–3, part V, many providers did not complete this worksheet. However, we believe we had a large enough sample to enable us to produce a reasonable Contract Labor cost weight. We continue to encourage all providers to report these data on the Medicare cost report.

Pharmaceuticals Costs

For freestanding IPFs, pharmaceuticals costs are based on non-salary costs reported on Worksheet A, column 7 less Worksheet A, column 1 for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73).

For hospital-based IPFs, pharmaceuticals costs are based on a portion of the non-salary pharmacy costs and a portion of the non-salary drugs charged to patient costs reported for the total facility. Non-salary pharmacy costs attributable to the hospital-based IPF are calculated by multiplying total pharmacy costs attributable to the hospital-based IPF (as reported on Worksheet B, column 15, line 40) by the ratio of total non-salary pharmacy costs (Worksheet A, column 2, line 15) to total pharmacy costs (sum of Worksheet A, column 1 and 2 for line 15) for the total facility. Non-salary drugs charged to patient costs attributable to the hospital-based IPF are calculated by multiplying total non-salary drugs charged to patient costs (Worksheet B, part I, column 0, line 73 plus Worksheet B, part I, column 15, line 73 less Worksheet A, column 1, line 73) for the total facility by the ratio of Medicare drugs charged to patient ancillary costs for the IPF unit (as reported on Worksheet D–3 for IPF subproviders, line 73, column 3) to total

Medicare drugs charged to patients ancillary costs for the total facility (equal to the sum of Worksheet D–3, line 73, column 3, for all relevant PPS (*i.e.* IPPS, IRF, IPF and SNF)).

Professional Liability Insurance (PLI) Costs

For freestanding IPFs, PLI costs (often referred to as malpractice costs) are equal to premiums, paid losses and self-insurance costs reported on Worksheet S–2, line 118, columns 1 through 3.

For hospital-based IPFs, we assume that the PLI weight for the total facility is similar to the hospital-based IPF unit since the only data reported on this worksheet is for the entire facility. Therefore, hospital-based IPF PLI costs are equal to total facility PLI (as reported on Worksheet S–2, line 118, columns 1 through 3) divided by total facility costs (as reported on Worksheet A, line 200) times hospital-based IPF Medicare allowable total costs.

Capital Costs

For freestanding IPFs, capital costs are equal to Medicare allowable capital costs as reported on Worksheet B, Part II, column 26.

For hospital-based IPFs, capital costs are equal to IPF inpatient capital costs (as reported on Worksheet B, part II, column 26, line 40) and a portion of IPF ancillary capital costs. We calculate the portion of ancillary capital costs attributable to the hospital-based IPF for a given cost center by multiplying total facility ancillary capital costs for the specific ancillary cost center (as reported on Worksheet B, Part II, column 26) by the ratio of IPF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for IPF subproviders) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant PPS (that is, IPPS, IRF, IPF and SNF)).

i. Final Major Cost Category Computation

After we derive costs for the six major cost categories for each provider using the Medicare cost report data as described above, we trim the data for outliers based on the following steps. First, we divide the costs for each of the six categories by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of IPF providers. Next, we apply a mutually exclusive top and bottom 5 percent trim for each cost weight to remove outliers. After the outliers have been removed, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2012-based IPF market basket for the given category. Finally, we calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the six cost categories listed above. See Table 1 below for the resulting cost weights for these major cost categories that we obtain from the Medicare cost reports.

TABLE 1—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

| Major cost categories | 2012-Based IPF (percent) | 2008-Based RPL (percent) |
|---|---|---|
| Wages and Salaries | 50.8 | 47.4 |
| Employee Benefits [1] | 13.0 | 12.3 |
| Contract Labor [1] | 1.4 | 2.6 |
| Professional Liability Insurance (Malpractice) | 1.1 | 0.8 |
| Pharmaceuticals | 4.8 | 6.5 |
| Capital | 7.0 | 8.4 |
| All Other | 22.0 | 22.0 |

* Total may not sum to 100 due to rounding.

[1] Due to the lack of Medicare cost report data, the Employee Benefits and Contract Labor cost weights in the 2008-based RPL market basket were based on the IPPS market basket.

The Wages and Salaries cost weight obtained directly from the Medicare cost reports for the proposed 2012-based IPF market basket is approximately 3 percentage points higher than the Wages and Salaries cost weight for the 2008-based RPL market basket. This is the result of freestanding IPFs having a larger percentage of costs attributable to labor than freestanding Inpatient Rehabilitation Facilities (IRF) and Long-term care hospitals. These latter facilities were included in the 2008-based RPL market basket.

As we did for the 2008-based RPL market basket, we propose to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The Contract Labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This rounded percentage is 80 percent; therefore, we propose to allocate 80 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 20 percent to the Employee Benefits cost weight. Table 2 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for both the proposed 2012-based IPF market basket and 2008-based RPL market basket.

TABLE 2—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

| Major cost categories | 2012-Based IPF | 2008-Based RPL |
|---|---|---|
| Wages and Salaries | 51.9 | 49.4 |
| Employee Benefits | 13.3 | 12.8 |

i. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the FY 2012 Medicare Cost Report data into more detailed cost categories, we propose to use the 2007 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for North American Industry Classification System (NAICS) 622000 Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following Web site: *http://www.bea.gov/industry/io_annual.htm.*

The BEA Benchmark I–O data are scheduled for publication every five years with the most recent data available for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Thus, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[1] BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we inflate the 2007 Benchmark I–O data forward to 2012 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeat this practice for each year. We then calculate the cost shares that each cost category represents of the inflated 2012 data. These resulting 2012 cost shares are applied to the All Other residual cost weight to obtain the detailed cost weights for the proposed 2012-based IPF market basket. For example, the cost for Food: Direct Purchases represents 6.5 percent of the sum of the ''All Other'' 2007 Benchmark I–O Hospital Expenditures inflated to 2012; therefore, the Food: Direct Purchases cost weight represents 6.5 percent of the 2012-based IPF market basket's ''All Other'' cost category (22.0 percent), yielding a ''final'' Food: Direct Purchases cost weight of 1.4 percent in the proposed 2012-based IPF market basket (0.065 * 22.0 percent = 1.4 percent).

Using this methodology, we derive eighteen detailed IPF market basket cost category weights from the proposed 2012-based IPF market basket residual cost weight (22.0 percent). These categories are: (1) Electricity, (2) Fuel, Oil, and Gasoline (3) Water & Sewerage (4) Food: Direct Purchases, (5) Food: Contract Services, (6) Chemicals, (7) Medical Instruments, (8) Rubber & Plastics, (9) Paper and Printing Products, (10) Miscellaneous Products, (11) Professional Fees: Labor-related, (12) Administrative and Facilities Support Services, (13) Installation, Maintenance, and Repair, (14) All Other Labor-related Services, (15) Professional Fees: Nonlabor-related, (16) Financial Services, (17) Telephone Services, and (18) All Other Nonlabor-related Services.

iii. Derivation of the Detailed Capital Cost Weights

As described in section III.A.3.a.i of this preamble, we are proposing a Capital-Related cost weight of 7.0 percent as obtained from the FY 2012 Medicare cost reports for freestanding and hospital-based IPF providers. We are proposing to then separate this total Capital-Related cost weight into more detailed cost categories.

Using FY 2012 Medicare cost reports, we are able to group Capital-Related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we are proposing to determine separately for hospital-based IPFs and freestanding IPFs what proportion of total capital-related costs the category represent.

For freestanding IPFs, we are proposing to derive the proportions for Depreciation, Interest, Lease, and Other Capital-related costs using the data reported by the IPF on Worksheet A–7, which is similar to the methodology used for the 2008-based RPL market basket.

For hospital-based IPFs, data for these four categories are not reported separately for the subprovider; therefore, we are proposing to derive these proportions using data reported on Worksheet A–7 for the total facility. We are assuming the cost shares for the overall hospital are representative for the hospital-based subprovider IPF unit. For example, if depreciation costs make up 60 percent of total capital costs for the entire facility, we believe it is reasonable to assume that the hospital-based IPF would also have a 60 percent proportion because it is a subprovider unit contained within the total facility.

In order to combine each detailed capital cost weight for freestanding and hospital-based IPFs into a single capital cost weight for the proposed 2012-based IPF market basket, we are proposing to weight together the shares for each of the categories (Depreciation, Interest, Lease, and Other Capital-related costs) based on the share of total capital costs each provider type represents of the total capital costs for all IPFs for 2012. Applying this methodology results in proportions of total capital-related costs for Depreciation, Interest, Lease and Other Capital-related costs that are representative of the universe of IPF providers.

We next are proposing to allocate lease costs across each of the remaining detailed capital-related cost categories as was done in the 2008-based RPL market basket. This would result in 3 primary capital-related cost categories in the proposed 2012-based IPF market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2012-based IPF market basket, but rather we are proposing to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done under the 2008-based RPL market basket, we are proposing to assume that 10 percent of the lease costs as a proportion of total capital-related costs represents overhead and assign those costs to the Other Capital-Related cost category accordingly. We propose to distribute the remaining lease costs proportionally across the 3 cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-related cost categories (excluding lease expenses). This is the same methodology used for the 2008-based RPL market basket. The allocation of these lease expenses are shown in Table 3 below.

Finally, we are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate Depreciation into the following 2 categories: (1) Building and Fixed Equipment; and (2) Movable Equipment; and proposing to separate Interest into the following 2 categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the Depreciation cost weight, we need to determine the percent of total Depreciation costs for IPFs that is attributable to Building and Fixed Equipment, which we hereafter refer to as the ''fixed percentage.'' For the proposed 2012-based IPF market basket, we are proposing to use slightly different methods to obtain the fixed

[1] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

percentages for hospital-based IPFs compared to freestanding IPFs.

For freestanding IPFs, we are proposing to use depreciation data from Worksheet A–7 of the FY 2012 Medicare cost reports, similar to the methodology used for the 2008-based RPL market basket. However, for hospital-based IPFs, we determined that the fixed percentage for the entire facility may not be representative of the IPF subprovider unit due to the entire facility likely employing more sophisticated movable assets that are not utilized by the hospital-based IPF. Therefore, for hospital-based IPFs, we are proposing to calculate a fixed percentage using: (1) Building and fixture capital costs allocated to the subprovider unit as reported on Worksheet B, part I line 40; and (2) building and fixture capital costs for the top five ancillary cost centers utilized by hospital-based IPFs. We propose to weight these 2 fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the proposed 2012-based IPF market basket. We are proposing to then weight the fixed percentages for hospital-based and freestanding IPFs together using the proportion of total capital costs each provider type represents.

To disaggregate the Interest cost weight, we need to determine the percent of total interest costs for IPFs that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage.'' For the IPF market basket, we are proposing to use interest costs data from Worksheet A–7 of the FY 2012 Medicare cost reports for both freestanding and hospital-based IPFs, similar to the methodology used for the 2008-based RPL market basket. We are proposing to determine the percent of total interest costs that are attributed to government and nonprofit IPFs separately for hospital-based and freestanding IPFs. We then are proposing to weight the nonprofit percentages for hospital-based and freestanding IPFs together using the proportion of total capital costs each provider type represents.

Table 3 below provides the detailed capital cost shares obtained from the Medicare cost reports. Ultimately, these detailed capital cost shares are applied to the total Capital-Related cost weight determined in section III.A.3.a.i to split out the total weight of 7.0 percent into more detailed cost categories and weights.

TABLE 3—DETAILED CAPITAL COST WEIGHTS FOR THE PROPOSED 2012-BASED IPF MARKET BASKET

| | Cost shares obtained from medicare cost reports percent | Proposed detailed capital cost shares after allocation of lease expenses percent |
|---|---|---|
| Depreciation | 64 | 75 |
| Building and Fixed Equipment | 46 | 53 |
| Movable Equipment | 19 | 22 |
| Interest | 15 | 17 |
| Government/Nonprofit | 12 | 14 |
| For Profit | 2 | 3 |
| Lease | 15 | n/a |
| Other | 6 | 8 |

v. Proposed 2012-Based IPF Market Basket Cost Categories and Weights

Table 4 below shows the cost categories and weights for the proposed 2012-based IPF market basket compared to the 2008-based RPL market basket.

TABLE 4—PROPOSED 2012-BASED IPF COST WEIGHTS COMPARED TO 2008-BASED RPL COST WEIGHTS

| Cost category | Proposed 2012-Based IPF cost weight | 2008-Based RPL cost weight |
|---|---|---|
| Total | 100.0 | 100.0 |
| Compensation | 65.2 | 62.3 |
| Wages and Salaries | 51.9 | 49.4 |
| Employee Benefits | 13.3 | 12.8 |
| Utilities | 1.8 | 1.6 |
| Electricity | 0.8 | 1.1 |
| Fuel, Oil, and Gasoline | 0.9 | 0.4 |
| Water & Sewerage | 0.1 | 0.1 |
| Professional Liability Insurance | 1.1 | 0.8 |
| Malpractice | 1.1 | 0.8 |
| All Other Products and Services | 25.0 | 27.0 |
| All Other Products | 11.7 | 15.6 |
| Pharmaceuticals | 4.8 | 6.5 |
| Food: Direct Purchases | 1.4 | 3.0 |
| Food: Contract Services | 0.9 | 0.4 |
| Chemicals | 0.6 | 1.1 |
| Medical Instruments | 1.9 | 1.8 |
| Rubber & Plastics | 0.5 | 1.1 |

TABLE 4—PROPOSED 2012-BASED IPF COST WEIGHTS COMPARED TO 2008-BASED RPL COST WEIGHTS—Continued

| Cost category | Proposed 2012-Based IPF cost weight | 2008-Based RPL cost weight |
|---|---|---|
| Paper and Printing Products | 1.0 | 1.0 |
| Apparel | ..... | 0.2 |
| Machinery and Equipment | ..... | 0.1 |
| Miscellaneous Products | 0.7 | 0.3 |
| All Other Services | 13.3 | 11.4 |
| Labor-Related Services | 6.7 | 4.7 |
| Professional Fees: Labor-related | 2.9 | 2.1 |
| Administrative and Facilities Support Services | 0.7 | 0.4 |
| Installation, Maintenance, and Repair | 1.6 | ..... |
| All Other: Labor-related Services | 1.5 | 2.1 |
| Nonlabor-Related Services | 6.6 | 6.7 |
| Professional Fees: Nonlabor-related | 2.6 | 4.2 |
| Financial services | 2.3 | 0.9 |
| Telephone Services | 0.6 | 0.4 |
| Postage | ..... | 0.6 |
| All Other: Nonlabor-related Services | 1.1 | 0.6 |
| Capital-Related Costs | 7.0 | 8.4 |
| Depreciation | 5.2 | 5.5 |
| Fixed Assets | 3.7 | 3.3 |
| Movable Equipment | 1.5 | 2.2 |
| Interest Costs | 1.2 | 2.0 |
| Government/Nonprofit | 1.0 | 0.7 |
| For Profit | 0.2 | 1.3 |
| Other Capital-Related Costs | 0.6 | 0.9 |
| Other Capital-Related Costs | 0.6 | 0.9 |

The proposed 2012-based IPF market basket does not include separate cost categories for Apparel, Machinery & Equipment, and Postage. Due to the small weights associated with these detailed categories and relatively stable price growth in the applicable price proxy, we are proposing to include Apparel and Machinery & Equipment in the Miscellaneous Products cost category and Postage in the All-Other Nonlabor-related Services. We note that these Machinery & Equipment expenses are for equipment that is paid for in a given year and not depreciated over the assets' useful life. Depreciation expenses for movable equipment are reflected in the Capital-related costs of the proposed 2012-based IPF market basket. For the proposed 2012-based IPF market basket, we are also proposing to include a separate cost category for Installation, Maintenance, and Repair.

b. Selection of Price Proxies

After developing the cost weights for the proposed 2012-based IPF market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

• *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

• *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

• *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

• *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

• *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly and, therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

• *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly

available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

• *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 6 lists all price proxies for the proposed 2012-based IPF market basket. Below is a detailed explanation of the price proxies we are proposing for each cost category weight.

i. Price Proxies for the Operating Portion of the Proposed 2012-Based IPF Market Basket

Wages and Salaries

To measure wage price growth in the proposed 2012-based IPF market basket, we are proposing to apply a proxy blend based on six occupational subcategories within the Wages and Salaries category, which would reflect the IPF occupational mix. There is not a published wage proxy for IPF workers. The 2008-based RPL market basket uses the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code #CIU1026220000000I) to proxy these expenses.

We propose to use the National Industry-Specific Occupational Employment and Wage estimates for North American Industrial Classification System (NAICS) 622200, Psychiatric & Substance Abuse Hospitals, published by the BLS Office of Occupational Employment Statistics (OES), as the data source for the wage cost shares in the wage proxy blend. We propose to use OES' May 2012 data. Detailed information on the methodology for the national industry-specific occupational employment and wage estimates survey can be found at *http://www.bls.gov/oes/current/oes_tec.htm*.

Based on the OES data, there are six wage subcategories: Management; NonHealth Professional and Technical; Health Professional and Technical; Health Service; NonHealth Service; and Clerical. Table 5 lists the proposed 2012 occupational assignments for the six wage subcategories.

TABLE 5—PROPOSED 2012 OCCUPATIONAL ASSIGNMENTS FOR IPF WAGE BLEND
2012 PROPOSED OCCUPATIONAL GROUPINGS

| Group 1 | Management |
|---|---|
| 11–0000 | Management Occupations. |
| **Group 2** | **NonHealth Professional & Technical** |
| 13–0000 | Business and Financial Operations Occupations. |
| 15–0000 | Computer and Mathematical Science Occupations. |
| 17–0000 | Architecture and Engineering Occupations. |
| 19–0000 | Life, Physical, and Social Science Occupations. |
| 23–0000 | Legal Occupations. |
| 25–0000 | Education, Training, and Library Occupations. |
| 27–0000 | Arts, Design, Entertainment, Sports, and Media Occupations. |
| **Group 3** | **Health Professional & Technical** |
| 29–1021 | Dentists, General. |
| 29–1031 | Dietitians and Nutritionists. |
| 29–1051 | Pharmacists. |
| 29–1062 | Family and General Practitioners. |
| 29–1063 | Internists, General. |
| 29–1069 | Physicians and Surgeons, All Other. |
| 29–1071 | Physician Assistants. |
| 29–1111 | Registered Nurses. |
| 29–1122 | Occupational Therapists. |
| 29–1123 | Physical Therapists. |
| 29–1125 | Recreational Therapists. |
| 29–1126 | Respiratory Therapists. |
| 29–1127 | Speech-Language Pathologists. |
| 29–1129 | Therapists, All Other. |
| 29–1199 | Health Diagnosing and Treating Practitioners, All Other. |
| **Group 4** | **Health Service** |
| 21–0000 | Community and Social Services Occupations. |
| 29–2011 | Medical and Clinical Laboratory Technologists. |
| 29–2012 | Medical and Clinical Laboratory Technicians. |
| 29–2021 | Dental Hygienists. |
| 29–2032 | Diagnostic Medical Sonographers. |
| 29–2034 | Radiologic Technologists and Technicians. |
| 29–2041 | Emergency Medical Technicians and Paramedics. |
| 29–2051 | Dietetic Technicians. |
| 29–2052 | Pharmacy Technicians. |
| 29–2054 | Respiratory Therapy Technicians. |
| 29–2061 | Licensed Practical and Licensed Vocational Nurses. |
| 29–2071 | Medical Records and Health Information Technicians. |
| 29–2099 | Health Technologists and Technicians, All Other. |
| 29–9012 | Occupational Health and Safety Technicians. |

TABLE 5—PROPOSED 2012 OCCUPATIONAL ASSIGNMENTS FOR IPF WAGE BLEND—Continued
2012 PROPOSED OCCUPATIONAL GROUPINGS

| | |
|---|---|
| 29–9099 | Healthcare Practitioner and Technical Workers, All Other. |
| 31–0000 | Healthcare Support Occupations. |
| Group 5 | NonHealth Service |
| 33–0000 | Protective Service Occupations. |
| 35–0000 | Food Preparation and Serving Related Occupations. |
| 37–0000 | Building and Grounds Cleaning and Maintenance Occupations. |
| 39–0000 | Personal Care and Service Occupations. |
| 41–0000 | Sales and Related Occupations. |
| 47–0000 | Construction and Extraction Occupations. |
| 49–0000 | Installation, Maintenance, and Repair Occupations. |
| 51–0000 | Production Occupations. |
| 53–0000 | Transportation and Material Moving Occupations. |
| Group 6 | Clerical |
| 43–0000 | Office and Administrative Support Occupations. |

Total expenditures by occupation (*i.e.,* occupational assignment) were calculated by taking the OES number of employees multiplied by the OES annual average salary. These expenditures were aggregated based on the six groups in Table 6. We next calculated the proportion of each group's expenditures relative to the total expenditures of all six groups. These proportions, listed in Table 5, represent the weights used in the wage proxy blend. We propose using the published wage proxies in Table 6 for each of the six groups (that is, wage subcategories) as we believe these six price proxies are the most technically appropriate indices available to measure the price growth of the Wages and Salaries cost category in the proposed 2012-based IPF market basket.

TABLE 6—PROPOSED 2012-BASED IPF MARKET BASKET WAGE PROXY BLEND

| Wage subcategory | Wage blend weight | Price proxy | BLS Series ID |
|---|---|---|---|
| Health Service | 36.2 | ECI for Wages and Salaries for All Civilian workers in Healthcare and Social Assistance. | CIU1026200000000I |
| Health Professional and Technical | 33.5 | ECI for Wages and Salaries for All Civilian workers in Hospitals | CIU1026220000000I |
| NonHealth Service | 9.2 | ECI for Wages and Salaries for Private Industry workers in Service Occupations. | CIU2020000300000I |
| NonHealth Professional and Technical. | 7.3 | ECI for Wages and Salaries for Private Industry workers in Professional, Scientific, and Technical Services. | CIU2025400000000I |
| Management | 7.1 | ECI for Wages and Salaries for Private Industry workers in Management, Business, and Financial. | CIU2020000110000I |
| Clerical | 6.7 | ECI for Wages and Salaries for Private Industry workers in Office and Administrative Support. | CIU2020000220000I |
| Total | 100.0 | | |

A comparison of the yearly changes from FY 2012 to FY 2015 for the proposed 2012-based IPF wage blend and the 2008-based RPL wage proxy is shown in Table 7. The average annual increase in the 2 price proxies is similar, and in no year is the difference greater than 0.2 percentage point.

TABLE 7—FISCAL YEAR GROWTH IN THE PROPOSED 2012-BASED IPF WAGE PROXY BLEND AND 2008-BASED RPL WAGE PROXY

| | 2012 | 2013 | 2014 | 2015 | Average 2012–2015 |
|---|---|---|---|---|---|
| 2012-based IPF Proposed Wage Proxy Blend | 1.6 | 1.6 | 1.6 | 2.2 | 1.8 |
| 2008-based RPL Wage Proxy | 1.5 | 1.5 | 1.5 | 2.0 | 1.6 |

** Source: IHS Global Insight, Inc., 1st Quarter 2015 forecast with historical data through 4th Quarter 2014.

Benefits

For measuring benefits price growth in the proposed 2012-based IPF market basket, we are proposing to apply a benefits proxy blend based on the same six subcategories and the same six blend weights proposed for the wage proxy blend. These subcategories and blend weights are listed in Table 8.

Applicable benefit ECIs, that are identical in industry definition to the wage blend ECIs, were selected for each of the six subcategories. These proposed benefit ECIs, listed in Table 8, are not publically available. Therefore, we calculated ''ECIs for Total Benefits'' using publically available ''ECIs for

Total Compensation'' for each subcategory and the relative importance of wages within that subcategory's total compensation. This is the same benefits ECI methodology we implemented in our IPPS, SNF, HHA, RPL, LTCH, and ESRD market baskets. We believe the six price proxies listed in Table 8 are the most technically appropriate indices to measure the price growth of the Benefits cost category in the proposed 2012-based IPF market basket.

The current 2008-based RPL market basket uses the ECI for Benefits for All Civilian Workers in Hospitals to proxy Benefit expenses.

TABLE 8—PROPOSED 2012-BASED IPF MARKET BASKET BENEFITS PROXY BLEND

| Wage subcategory | Wage blend weight | Price proxy |
|---|---|---|
| Health Service | 36.2 | ECI for Total Benefits for All Civilian workers in Healthcare and Social Assistance. |
| Health Professional and Technical | 33.5 | ECI for Total Benefits for All Civilian workers in Hospitals. |
| NonHealth Service | 9.2 | ECI for Total Benefits for Private Industry workers in Service Occupations. |
| NonHealth Professional and Technical | 7.3 | ECI for Total Benefits for Private Industry workers in Professional, Scientific, and Technical Services. |
| Management | 7.1 | ECI for Total Benefits for Private Industry workers in Management, Business, and Financial. |
| Clerical | 6.7 | ECI for Total Benefits for Private Industry workers in Office and Administrative Support. |
| Total | 100.0 | |

A comparison of the yearly changes from FY 2012 to FY 2015 for the proposed 2012-based IPF benefit proxy blend and the 2008-based RPL benefit proxy is shown in Table 9. The average annual increase in the 2 price proxies is similar, and in no year is the difference greater than 0.4 percentage point.

TABLE 9—FISCAL YEAR GROWTH IN THE PROPOSED 2012-BASED IPF BENEFIT PROXY BLEND AND 2008-BASED RPL BENEFIT PROXY

| | 2012 | 2013 | 2014 | 2015 | Average 2012–2015 |
|---|---|---|---|---|---|
| 2012-based IPF Proposed Benefit Proxy Blend | 2.5 | 1.9 | 2.0 | 2.2 | 2.2 |
| 2008-based RPL Benefit Proxy | 2.1 | 1.8 | 2.1 | 2.1 | 2.0 |

Source: IHS Global Insight, Inc., 1st Quarter 2015 forecast with historical data through 4th Quarter 2014.

Electricity

We are proposing to continue to use the PPI for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2008-based RPL market basket.

Fuel, Oil, and Gasoline

We are proposing to change the proxy used for the Fuel, Oil, and Gasoline cost category. The 2008-based RPL market basket uses the PPI for Petroleum Refineries (BLS series code #PCU32411–32411) to proxy these expenses.

For the proposed 2012-based IPF market basket, we are proposing to use a blend of the PPI for Petroleum Refineries and the PPI Commodity for Natural Gas (BLS series code #WPU0531). Our analysis of the Bureau of Economic Analysis' 2007 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that Petroleum Refineries expenses accounts for approximately 70 percent and Natural Gas accounts for approximately 30 percent of the Fuel, Oil, and Gasoline expenses. Therefore, we propose a blend using 70 percent of the PPI for Petroleum Refineries (BLS series code #PCU32411–32411) and 30 percent of the PPI Commodity for Natural Gas (BLS series code #WPU0531). We believe that these 2 price proxies are the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the proposed 2012-based IPF market basket.

Water and Sewerage

We are proposing to continue to use the CPI for Water and Sewerage Maintenance (BLS series code #CUUR0000SEHG01) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Professional Liability Insurance

We are proposing to continue to use the CMS Hospital Professional Liability Index to measure changes in professional liability insurance (PLI) premiums. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2008-based RPL market basket.

Pharmaceuticals

We are proposing to continue to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code #WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Food: Direct Purchases

We are proposing to continue to use the PPI for Processed Foods and Feeds (BLS series code #WPU02) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Food: Contract Purchases

We are proposing to continue to use the CPI for Food Away From Home (BLS series code #CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Chemicals

We are proposing to continue to use a four part blended PPI composed of the PPI for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code #PCU32518–32518), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code #PCU32519–32519), and the PPI for Soap and Cleaning Compound Manufacturing (BLS series code #PCU32561–32561). We propose updating the blend weights using 2007 Benchmark I–O data which, compared to 2002 Benchmark I–O data, is weighted more toward organic chemical products and weighted less toward inorganic chemical products.

Table 10 below shows the proposed weights for each of the four PPIs used to create the blended PPI. These are the same four proxies used in the 2008-based RPL market basket; however, the blended PPI weights in the 2008-based RPL market baskets were based on 2002 Benchmark I–O data.

TABLE 10—BLENDED CHEMICAL PPI WEIGHTS

| Name | Proposed 2012-Based IPF weights (percent) | 2008-Based RPL weights (percent) | NAICS |
|---|---|---|---|
| PPI for Industrial Gas Manufacturing | 32 | 35 | 325120 |
| PPI for Other Basic Inorganic Chemical Manufacturing | 17 | 25 | 325180 |
| PPI for Other Basic Organic Chemical Manufacturing | 45 | 30 | 325190 |
| PPI for Soap and Cleaning Compound Manufacturing | 6 | 10 | 325610 |

Medical Instruments

We are proposing to use a blend for the Medical Instruments cost category. The 2007 Benchmark Input-Output data shows an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we propose a blend composed of 50 percent of the commodity-based PPI for Surgical and Medical Instruments (BLS code #WPU1562) and 50 percent of the commodity-based PPI for Medical and Surgical Appliances and Supplies (BLS code #WPU1563). The 2008-based RPL market basket uses the single, higher level PPI for Medical, Surgical, and Personal Aid Devices (BLS series code #WPU156).

Rubber and Plastics

We are proposing to continue to use the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Paper and Printing Products

We are proposing to continue to use the PPI for Converted Paper and Paperboard Products (BLS series code #WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Miscellaneous Products

We are proposing to continue to use the PPI for Finished Goods Less Food and Energy (BLS series code #WPUSOP3500) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Professional Fees: Labor-Related

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2008-based RPL market basket.

Administrative and Facilities Support Services

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code #CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2008-based RPL market basket.

Installation, Maintenance, and Repair

We are proposing to use the ECI for Total Compensation for Civilian workers in Installation, Maintenance, and Repair (BLS series code #CIU1010000430000I) to measure the price growth of this new cost category. Previously these costs were included in the All Other: Labor-related Services category and were proxied by the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code #CIU2010000300000I). We believe that this index better reflects the price changes of labor associated with maintenance-related services and its incorporation represents a technical improvement to the market basket.

All Other: Labor-Related Services

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code #CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Professional Fees: Nonlabor-Related

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2008-based RPL market basket.

Financial Services

We are proposing to continue to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code #CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

Telephone Services

We are proposing to continue to use the CPI for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

All Other: Nonlabor-Related Services

We are proposing to continue to use the CPI for All Items Less Food and Energy (BLS series code #CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2008-based RPL market basket.

ii. Price Proxies for the Capital Portion of the Proposed 2012-Based IPF Market Basket

Capital Price Proxies Prior to Vintage Weighting

We are proposing to apply the same price proxies to the detailed capital-related cost categories as were applied in the 2008-based RPL market basket, which are provided in Table 12 and described below. We are also proposing to continue to vintage weight the capital price proxies for Depreciation and Interest in order to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2008-based RPL market basket and is described below.

We are proposing to proxy the Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). We are proposing to proxy the Depreciation: Movable Equipment cost category by the PPI for Machinery and Equipment (BLS series code #WPU11). We are proposing to proxy the Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index). We are proposing to proxy the For-profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve). We are proposing to proxy the Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code #CUUS0000SEHA). We believe these are the most appropriate proxies for IPF capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2012-based IPF market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual non-vintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for IPF capital-related costs. The capital-related component of the proposed 2012-based IPF market basket reflects the underlying stability of the capital-related acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, the AHA does provide a consistent database of total expenses back to 1963. Consequently, we are proposing to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We are then proposing to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2012. We propose to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined above. From these annual depreciation amounts we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to IPFs, we believe this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for IPFs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also need the expected lives for Building and Fixed Equipment, Movable Equipment, and Interest for the proposed 2012-based IPF market basket. We are proposing to calculate the expected lives using Medicare cost report data from freestanding and hospital-based IPFs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We are proposing to determine the expected life of building and fixed equipment separately for hospital-based IPFs and freestanding IPFs and weight these expected lives using the percent of total capital costs each provider type represents. We are proposing to apply a similar method for movable equipment. Using these proposed methods, we determined the average expected life of building and fixed equipment to be equal to 23 years, and the average expected life of movable equipment to be equal to 11 years. For the expected life of interest, we believe vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2008-based RPL market basket, we used FY 2008 Medicare cost reports for IPPS hospitals to determine the expected life of building and fixed equipment and movable equipment (76 FR 51763). The 2008-based RPL market basket was based on an expected average life of building and fixed equipment of 26 years and an expected average life of movable equipment of 11 years, which were both calculated using data for IPPS hospitals.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculate a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we are proposing to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price

proxy as provided above. For the interest vintage weights, we are proposing to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we are proposing to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 23 years, and in the case of movable equipment, 11 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2012 back to 1964. These data allow us to derive twenty-seven 23-year periods of capital-related purchases for building and fixed equipment and interest, and thirty-nine 11-year periods of capital-related purchases for movable equipment. For each 23-year period for building and fixed equipment and interest, or 11-year period for movable equipment, we calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 23-year or 11-year period. This calculation is done for each year in the 23-year or 11-year period and for each of the periods for which we have data. We then calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data. The vintage weights for the capital-related portion of the 2008-based RPL market basket and the proposed 2012-based IPF market basket are presented in Table 11 below.

TABLE 11—2008-BASED RPL MARKET BASKET AND PROPOSED 2012-BASED IPF MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

| Year | Building and fixed equipment | | Movable equipment | | Interest | |
|---|---|---|---|---|---|---|
| | 2012-based 23 years | 2008-based 26 years | 2012-based 11 years | 2008-based 11 years | 2012-based 23 years | 2008-based 26 years |
| 1 | 0.029 | 0.021 | 0.069 | 0.071 | 0.017 | 0.010 |
| 2 | 0.031 | 0.023 | 0.073 | 0.075 | 0.019 | 0.012 |
| 3 | 0.034 | 0.025 | 0.077 | 0.080 | 0.022 | 0.014 |
| 4 | 0.036 | 0.027 | 0.083 | 0.083 | 0.024 | 0.016 |
| 5 | 0.037 | 0.028 | 0.087 | 0.085 | 0.026 | 0.018 |
| 6 | 0.039 | 0.030 | 0.091 | 0.089 | 0.028 | 0.020 |
| 7 | 0.040 | 0.031 | 0.096 | 0.092 | 0.030 | 0.021 |
| 8 | 0.041 | 0.033 | 0.100 | 0.098 | 0.032 | 0.024 |
| 9 | 0.042 | 0.035 | 0.103 | 0.103 | 0.035 | 0.026 |
| 10 | 0.044 | 0.037 | 0.107 | 0.109 | 0.038 | 0.029 |
| 11 | 0.045 | 0.039 | 0.114 | 0.116 | 0.040 | 0.033 |
| 12 | 0.045 | 0.041 | | | 0.042 | 0.035 |
| 13 | 0.045 | 0.042 | | | 0.044 | 0.038 |
| 14 | 0.046 | 0.043 | | | 0.046 | 0.041 |
| 15 | 0.046 | 0.044 | | | 0.048 | 0.043 |
| 16 | 0.048 | 0.045 | | | 0.053 | 0.046 |
| 17 | 0.049 | 0.046 | | | 0.057 | 0.049 |
| 18 | 0.050 | 0.047 | | | 0.060 | 0.052 |
| 19 | 0.051 | 0.047 | | | 0.063 | 0.053 |
| 20 | 0.051 | 0.045 | | | 0.066 | 0.053 |
| 21 | 0.051 | 0.045 | | | 0.067 | 0.055 |
| 22 | 0.050 | 0.045 | | | 0.069 | 0.056 |
| 23 | 0.052 | 0.046 | | | 0.073 | 0.060 |
| 24 | | 0.046 | | | | 0.063 |
| 25 | | 0.045 | | | | 0.064 |
| 26 | | 0.046 | | | | 0.068 |
| Total | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 |

**Note:** Numbers may not add to total due to rounding.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table 11 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

iii. Summary of Price Proxies of the Proposed 2012-Based IPF Market Basket

Table 12 shows both the operating and capital price proxies for the proposed 2012-based IPF Market Basket.

TABLE 12—PRICE PROXIES FOR THE PROPOSED 2012-BASED IPF MARKET BASKET

| Cost description | Price proxies | Weight (percent) |
|---|---|---|
| Total | | 100.0 |

TABLE 12—PRICE PROXIES FOR THE PROPOSED 2012-BASED IPF MARKET BASKET—Continued

| Cost description | Price proxies | Weight (percent) |
|---|---|---|
| Compensation | | 65.2 |
| Wages and Salaries | Blended Wages and Salaries Price Proxy | 51.9 |
| Employee Benefits | Blended Benefits Price Proxy | 13.3 |
| Utilities | | 1.8 |
| Electricity | PPI for Commercial Electric Power | 0.8 |
| Fuel, Oil, and Gasoline | Blend of the PPI for Petroleum Refineries and PPI for Natural Gas | 0.9 |
| Water & Sewerage | CPI–U for Water and Sewerage Maintenance | 0.1 |
| Professional Liability Insurance | | 1.1 |
| Malpractice | CMS Hospital Professional Liability Insurance Premium Index | 1.1 |
| All Other Products and Services | | 25.0 |
| All Other Products | | 11.7 |
| Pharmaceuticals | PPI for Pharmaceuticals for human use, prescription | 4.8 |
| Food: Direct Purchases | PPI for Processed Foods and Feeds | 1.4 |
| Food: Contract Services | CPI–U for Food Away From Home | 0.9 |
| Chemicals | Blend of Chemical PPIs | 0.6 |
| Medical Instruments | Blend of the PPI for Surgical and medical instruments and PPI for Medical and surgical appliances and supplies. | 1.9 |
| Rubber & Plastics | PPI for Rubber and Plastic Products | 0.5 |
| Paper and Printing Products | PPI for Converted Paper and Paperboard Products | 1.0 |
| Miscellaneous Products | PPI for Finished Goods Less Food and Energy | 0.7 |
| All Other Services | | 13.3 |
| Labor-Related Services | | 6.7 |
| Professional Fees: Labor-related | ECI for Total compensation for Private industry workers in Professional and related | 2.9 |
| Administrative and Facilities Support Services. | ECI for Total compensation for Private industry workers in Office and administrative support. | 0.7 |
| Installation, Maintenance, and Repair. | ECI for Total compensation for Civilian workers in Installation, maintenance, and repair. | 1.6 |
| All Other: Labor-related Services | ECI for Total compensation for Private industry workers in Service occupations | 1.5 |
| Nonlabor-Related Services | | 6.6 |
| Professional Fees: Nonlabor-related. | ECI for Total compensation for Private industry workers in Professional and related | 2.6 |
| Financial services | ECI for Total compensation for Private industry workers in Financial activities | 2.3 |
| Telephone Services | CPI–U for Telephone Services | 0.6 |
| All Other: Nonlabor-related Services. | CPI–U for All Items Less Food and Energy | 1.1 |
| Capital-Related Costs | | 7.0 |
| Depreciation | | 5.2 |
| Fixed Assets | BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (23 years). | 3.7 |
| Movable Equipment | PPI for machinery and equipment—vintage weighted (11 years) | 1.5 |
| Interest Costs | | 1.2 |
| Government/Nonprofit | Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage weighted (23 years). | 1.0 |
| For Profit | Average yield on Moody's Aaa bonds—vintage weighted (23 years) | 0.2 |
| Other Capital-Related Costs | CPI–U for Rent of primary residence | 0.6 |

**Note:** Totals may not sum to 100.0 percent due to rounding.

4. Proposed FY 2016 Market Basket Update

For FY 2016 (that is, beginning October 1, 2015 and ending September 30, 2016), we are proposing to use an estimate of the proposed 2012-based IPF market basket increase factor to update the IPF PPS base payment rate. Consistent with historical practice, we estimate the market basket update for the IPF PPS based on IHS Global Insight's forecast using the most recent available data. IHS Global Insight (IGI), Inc. is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's first quarter 2015 forecast with historical data through the fourth quarter of 2014, the projected proposed 2012-based IPF market basket increase factor for FY 2016 is 2.7 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket increase factor of 2.7 percent for FY 2016. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket) we would use such data, to determine the FY 2016 update in the final rule.

For comparison, the current 2008-based RPL market basket is projected to increase by 2.8 percent in FY 2016 based on IGI's first quarter 2015 forecast. Table 13 compares the proposed 2012-based IPF market basket and the 2008-based RPL market basket percent changes.

TABLE 13—PROPOSED 2012-BASED IPF MARKET BASKET AND 2008-BASED RPL MARKET BASKET PERCENT CHANGES, FY 2010 THROUGH FY 2018

| Fiscal Year (FY) | Proposed 2012-Based IPF market basket index percent change | 2008-Based RPL market basket index percent change |
|---|---|---|
| Historical data: | | |
| FY 2010 | 2.0 | 2.2 |
| FY 2011 | 2.2 | 2.5 |
| FY 2012 | 1.9 | 2.2 |
| FY 2013 | 2.0 | 2.1 |
| FY 2014 | 1.9 | 1.8 |
| Average 2010–2014 | 2.0 | 2.2 |
| Forecast: | | |
| FY 2015 | 2.0 | 2.2 |
| FY 2016 | 2.7 | 2.8 |
| FY 2017 | 3.0 | 3.0 |
| FY 2018 | 3.0 | 3.1 |
| Average 2015–2018 | 2.7 | 2.8 |

**Note:** These market basket percent changes do not include any further adjustments as may be statutorily required. Source: IHS Global Insight, Inc. 1st quarter 2015 forecast.

For FY 2016, the proposed 2012-based IPF market basket update (2.7 percent) is one tenth of a percentage point lower than the 2008-based RPL market basket (2.8 percent). The 0.1 percentage point difference stems from the lower Pharmaceuticals cost weight in the proposed 2012-based IPF market basket (4.8 percent) compared to the 2008-based RPL market basket (6.5 percent) as well as from the use of the blended price proxies for the Wages and Salaries and Employee Benefits cost categories.

5. Proposed Productivity Adjustment

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) publishes the official measure of private non-farm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As described in the FY 2012 IPPS/LTCH final rule (76 FR 51690 through 51692), in order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the FY 2012 rule, we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the FY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. Although we discuss the IGI changes to the MFP proxy series in this proposed rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

Using IGI's first quarter 2015 forecast, the MFP adjustment for FY 2016 (the 10-year moving average of MFP for the period ending FY 2016) is projected to be 0.6 percent. Thus, in accordance with section 1886(s)(2)(A)(i) of the Act, we propose to base the FY 2016 market basket update, which is used to determine the applicable percentage increase for the IPF payments, on the most recent estimate of the proposed 2012-based IPF market basket (currently estimated to be 2.7 percent based on IGI's first quarter 2015 forecast). We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2016 of 0.6 percentage point (the 10-year moving average of MFP for the period ending FY 2016 based on IGI's first quarter 2015 forecast). Furthermore, we also propose 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 to determine the FY 2016 market basket update and MFP adjustment in the final rule.

Section 1886(s)(2)(A)(ii) of the Act requires the application of an ''other adjustment'' that reduces any update to an IPF PPS base rate by percentages specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. For the RY beginning in 2015 (that is, FY 2016), section 1886(s)(3)(D) of the Act requires the reduction to be 0.2 percentage point. We are proposing to implement the productivity adjustment and 'other adjustment' in this FY 2016 IPF PPS

proposed rule. We invite public comment on these proposals.

6. Proposed Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. As stated in the FY 2015 IPF PPS final rule (79 FR 45943), the labor-related share was defined as the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor- Related Services, Administrative and Facilities Support Services, All Other: Labor-related Services, and a portion of the Capital Costs from the 2008-based RPL market basket.

Based on our definition of the labor-related share and the cost categories in the proposed 2012-based IPF market basket, we are proposing to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor- Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair, All Other: Labor-related Services, and a portion of the Capital-Related cost weight from the proposed 2012-based IPF market basket. As noted in Section III.A.3.b.i of this proposed rule, for the proposed 2012-based IPF market basket, we have created a separate cost category for Installation, Maintenance and Repair services. These expenses were previously included in the ''All Other'' Labor-related Services cost category in the 2008-based RPL market basket, along with other services, including but not limited to janitorial, waste management, security, and dry cleaning/laundry services. Because these services tend to be labor-intensive and are mostly performed at the facility (and, therefore, unlikely to be purchased in the national market), we continue to believe that they meet our definition of labor-related services.

Similar to the 2008-based RPL market basket, the proposed 2012-based IPF market basket includes 2 cost categories for nonmedical Professional fees (including but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-related and Professional Fees: Nonlabor-related. For the proposed 2012-based IPF market basket, we propose to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2008-based RPL market basket.

To summarize, the professional services survey found that hospitals purchase the following proportion of these four services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We applied each of these percentages to the respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the same methodology that we used to separate the 2008-based RPL market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. For more detail regarding this methodology see the FY 2012 IPF final rule (76 FR 26445).

In addition to the professional services listed above, we also classified expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees cost category as was done in the 2008-based RPL market basket. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. Since many facilities are not located in the same geographic area as their home office, we analyzed data from a variety of sources in order to determine what proportion of these costs should be appropriately included in the labor-related share. For the 2012-based IPF market basket, we are proposing to derive the home office percentages using data for both freestanding IPF providers and hospital-based IPF providers. In the 2008-based RPL market basket, we used the home office percentages based on the data reported by freestanding IRFs, IPFs, and LTCHs. Using data primarily from the Medicare cost reports and the Home Office Medicare Records (HOMER) database that provides the address (including city and state) for home offices, we were able to determine that 36 percent of the total number of freestanding and hospital-based IPFs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA).

The Medicare cost report requires hospitals to report their home office provider numbers. Using the HOMER database to determine the home office location for each home office provider number, we compared the location of the provider with the location of the hospital's home office. We then placed providers into one of the following 2 groups:

- Group 1—Provider and home office are located in different MSAs.
- Group 2—Provider and home office are located in the same MSA.

We found that 64 percent of the providers with home offices were classified into Group 1 (that is, different MSA) and, thus, these providers were determined to not be located in the same local labor market as their home office. We found that 36 percent of all providers with home offices were classified into Group 2 (that is, the same MSA). Given these results, we are proposing to classify 36 percent of the Professional Fees costs into the Professional Fees: Labor-related cost category and the remaining 64 percent into the Professional Fees: Nonlabor-related Services cost category. This methodology for apportioning the Professional Fee expenses between labor-related and nonlabor-related categories is similar to the method used in the 2008-based RPL market basket (see 76 FR 26445).

Using this proposed method and the IHS Global Insight, Inc. 4th quarter 2014 forecast for the proposed 2012-based IPF market basket, the proposed IPF labor-related share for FY 2016 is the sum of the FY 2016 relative importance of each labor-related cost category. The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2012) and FY 2016. Table 14 shows the proposed FY 2016 labor-related share using the proposed 2012-based IPF market basket relative importance and the FY 2015 labor-related share using the 2008-based RPL market basket.

The sum of the relative importance for FY 2016 operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services) is 71.8 percent, as

shown in Table 14. We are proposing to specify the labor-related share to one decimal place, which is consistent with the IPPS labor-related share (currently the Labor-related share from the RPL market basket is specified to 3 decimal places).

We are proposing that the portion of Capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2008-based RPL market basket. Since the relative importance for Capital-Related Costs is 6.8 percent of the proposed 2012-based IPF market basket in FY 2016, we are proposing to take 46 percent of 6.8 percent to determine the proposed labor-related share of Capital for 2016. The result would be 3.1 percent, which we propose to add to 71.8 percent for the operating cost amount to determine the total proposed labor-related share for FY 2016.

The FY 2016 labor-related share using the proposed 2012-based IPF market basket is about five percentage points higher than the FY 2015 labor-related share using the 2008-based RPL market basket. Of the five percentage point difference, 3 percentage points is attributable to the higher Wages and Salaries and Employee Benefits cost weights in the 2012-based IPF market basket compared to the 2008-based RPL market basket, while 2 percentage points is attributable to the higher weight associated with the labor-related services cost categories. We would note that the higher Wages and Salaries cost weight in the 2012-based IPF market basket relative to the 2008-based RPL market basket is the result of freestanding IPFs having a larger percentage of costs attributable to labor than freestanding IRFs and Long-term care hospitals. These latter facilities were included in the 2008-based RPL market basket.

TABLE 14—PROPOSED 2016 IPF LABOR-RELATED SHARE

| | FY 2016 labor-related share based on proposed 2012-based IPF market basket [1] | FY 2015 final labor-related share [2] |
|---|---|---|
| Wages and Salaries | 51.7 | 48.271 |
| Employee Benefits | 13.4 | 12.936 |
| Professional Fees: Labor-related | 2.9 | 2.058 |
| Administrative and Facilities Support Services | 0.7 | 0.415 |
| Installation, Maintenance and Repair | 1.6 | ..... |
| All Other: Labor-related Services | 1.5 | 2.061 |
| Subtotal | 71.8 | 65.741 |
| Labor-related portion of capital (46%) | 3.1 | 3.553 |
| Total LRS | 74.9 | 69.294 |

[1] IHS Global Insight, Inc. 4th quarter 2014 forecast.
[2] **Federal Register** 79–FR–45943.

In weighing the effects of the change in the LRS, we considered whether to recommend a 2-year transitional implementation of the increase in the LRS. We recognize that IPFs with wage index values of less than one would be adversely affected by an increased LRS, as a larger share of the base rate would be adjusted by the wage index value. About 69 percent of IPFs would have wage index values of less than one using FY2015 CBSA data, and 30 percent of these providers are rural. While the LRS would be updated in a budget neutral fashion so that the overall impact on payments is zero, there would still be distributional effects on specific categories of IPFs. We considered the distributional effects of the multiple proposals made in this proposed rule, including the proposal to update the full LRS in FY 2016, and we found that the negative impact of updating the LRS in a single year, without a transition, was relatively small, as shown in Table 26 in section VII. of this proposed rule. Additionally, we are proposing 2 other adjustments to benefit providers: A transitional wage index and a phase-out of the 17 percent rural adjustment for the 37 IPFs that would change from rural to urban status due to the new CBSA delineations. As presented in section III.A.6. of this proposed rule, we are proposing to use the 2012-based IPF market basket relative importance's to determine the FY 2016 IPF LRS. We believe this is technically appropriate as it is based on more recent, provider-specific data for IPFs. For all of these reasons, we propose to implement the full LRS in FY 2016, but solicit comments on this issue.

*B. Proposed Updates to the IPF PPS for FY 2016 (Beginning October 1, 2015)*

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget-neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the November 2004 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget-Neutral Federal Per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget-neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (that is, October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. Additional information concerning this standardization can be found in the November 2004 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget-neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the May 2006 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget-neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be $575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and § 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget-neutral Federal per diem base rate and the electroconvulsive therapy (ECT) rate appears in the August 2013 IPF PPS update notice (78 FR 46738 through 46739). These documents are available on the CMS Web site at *http://www.cms.hhs.gov/InpatientPsychFacilPPS/*.

2. Proposed FY 2016 Update of the Federal Per Diem Base Rate and Electroconvulsive Therapy (ECT) Rate

The current (that is, FY 2015) Federal per diem base rate is $728.31 and the ECT rate is $313.55. For FY 2016, we are proposing to apply an update of 1.9 percent (that is, the proposed FY 2012-based IPF-specific market basket increase for FY 2016 of 2.7 percent less the proposed productivity adjustment of 0.6 percentage point, and further reduced by the 0.2 percentage point required under section1886(s)(3)(D) of the Act), and the wage index budget-neutrality factor of 1.0041 (as discussed in section III.D.1.e. of this proposed rule) to the FY 2015 Federal per diem base rate of $728.31, yielding a proposed Federal per diem base rate of $745.19 for FY 2016. Similarly, we are proposing to apply the 1.9 percent payment update and the 1.0041 wage index budget-neutrality factor to the FY 2015 ECT rate, yielding a proposed ECT rate of $320.82 for FY 2016.

As noted above, section 1886(s)(4) of the Act requires the establishment of a quality data reporting program for the IPF PPS beginning in RY 2015. We refer readers to section V. of this proposed rule for a discussion of the IPF Quality Reporting Program. Section 1886(s)(4)(A)(i) of the Act requires that, for RY 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during the rate year by 2.0 percentage points for any IPF that does not comply with the quality data submission requirements with respect to an applicable year. Therefore, we are proposing to apply a 2.0 percentage point reduction to the Federal per diem base rate and the ECT rate as follows:

For IPFs that failed to submit quality reporting data under the IPFQR program, we would apply a −0.1 percent annual update (that is, 1.9 percent reduced by 2 percentage points, in accordance with section 1886(s)(4)(A)(ii) of the Act) and the wage index budget-neutrality factor of 1.0041 to the FY 2015 Federal per diem base rate of $728.31, yielding a Federal per diem base rate of $730.56 for FY 2016.

Similarly, we would apply the −0.1 percent annual update and the 1.0041 wage index budget-neutrality factor to the FY 2015 ECT rate of $313.55, yielding an ECT rate of $314.52 for FY 2016.

*C. Proposed Updates to the IPF PPS Patient-Level Adjustment Factors*

1. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 MedPAR data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). While we have since used more recent claims data to simulate payments to set the fixed dollar loss threshold amount for the outlier policy and to assess the impact of the IPF PPS updates, we continue to use the regression-derived adjustment factors established in 2005 for FY 2016.

2. IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS–DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

a. MS–DRG Assignment

We believe it is important to maintain the same diagnostic coding and DRG classification for IPFs that are used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD–9–CM) and DRG patient classification system (that is, the CMS DRGs) that were utilized at the time under the IPPS. In the May 2008 IPF PPS notice (73 FR 25709), we discussed CMS's effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS–DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the 2008 IPF PPS notice (73 FR 25716), we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS–DRGs. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS–DRG adjustment categories, we refer readers to the May 2008 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis. Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF–MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment.

For the FY 2016 update, we are not proposing any changes to the IPF MS–DRG adjustment factors. In FY 2015 rulemaking (79 FR 45945 through 45947), we proposed and finalized conversions of the ICD–9–CM-based MS–DRGs to ICD–10–CM/PCS-based MS–DRGs, which will be implemented on October 1, 2015. Further information for the ICD–10–CM/PCS MS–DRG conversion project can be found on the

CMS ICD–10–CM Web site at *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*.

For FY 2016, we propose to continue to make a payment adjustment for psychiatric diagnoses that group to one of the existing 17 MS–IPF–DRGs listed in the Addendum. Psychiatric principal diagnoses that do not group to one of the 17 designated DRGs would still receive the Federal per diem base rate and all other applicable adjustments, but the payment would not include a DRG adjustment.

As noted above, the diagnoses for each IPF MS–DRG will be updated on October 1, 2015, using the ICD–10–CM/PCS code sets.

b. Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain concurrent medical or psychiatric conditions that are expensive to treat. In the May 2011 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD–9–CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for claims for discharges on or after October 1, 2015 require IPFs to enter the complete ICD–10–CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD–9–CM ''code first'' instructions apply. As we explained in the May 2011 IPF PPS final rule (76 FR 265451), the ''code first'' rule applies when a condition has both an underlying etiology and a manifestation due to the underlying etiology. For these conditions, ICD–9–CM has a coding convention that requires the underlying conditions to be sequenced first followed by the manifestation. Whenever a combination exists, there is a ''use additional code'' note at the etiology code and a ''code first'' note at the manifestation code.

The same principle holds for ICD–10–CM as for ICD–9–CM. Whenever a combination exists, there is a ''use additional code'' note in the ICD–10–CM codebook pertaining to the etiology code, and a ''code first'' code pertaining to the manifestation code. In the FY 2015 IPF PPS final rule, we provided a ''code first'' table for reference that highlights the same or similar manifestation codes where the ''code first'' instructions apply in ICD–10–CM that were present in ICD–9–CM (79 FR 46009).

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD–9–CM codes were converted to ICD–10–CM/PCS in the FY 2015 IPF PPS final rule (79 FR 45947 to 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD–10–CM implementation as it would be if the same record had been coded in ICD–9–CM and submitted prior to ICD–10–CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal.

We are not proposing any refinements to the comorbidity adjustments at this time, and propose to continue to use the existing adjustments in effect in FY 2015. The FY 2016 comorbidity adjustments are found in the Addendum to this proposed rule.

3. Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (that is, the range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are more costly than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant.

For FY 2016, we are proposing to continue to use the patient age adjustments currently in effect in FY 2015, as shown in the Addendum to this proposed rule.

4. Variable Per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF.

We used a regression analysis to estimate the average differences in per diem cost among stays of different lengths. As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying emergency department (ED). If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section III.D.4. of this proposed rule.

For FY 2016, we propose to continue to use the variable per diem adjustment factors currently in effect as shown in the Addendum to this proposed rule. A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

*D. Proposed Updates to the IPF PPS Facility-Level Adjustments*

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Proposed Wage Index Adjustment

a. Background

As discussed in the May 2006 IPF PPS final rule (71 FR 27061) and in the May 2008 (73 FR 25719) and May 2009 IPF PPS notices (74 FR 20373), in order to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location

of the IPF in an urban or rural area as defined in § 412.64(b)(1)(ii)(A) and (C).

b. Proposed Wage Index for FY 2016

Since the inception of the IPF PPS, we have used the pre-floor, pre-reclassified acute care hospital wage index in developing a wage index to be applied to IPFs because there is not an IPF-specific wage index available. We believe that IPFs generally compete in the same labor markets as acute care hospitals, so the pre-floor, pre-reclassified hospital wage index should reflect IPF labor costs. As discussed in the May 2006 IPF PPS final rule for FY 2007 (71 FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without taking into account geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, please see the CY 2013 IPPS/LTCH PPS final rule (77 FR 53365 through 53374). For FY 2016, we are proposing to continue to apply the most recent hospital wage index (that is, the FY 2015 pre-floor, pre-reclassified hospital wage index, which is the most appropriate index as it best reflects the variation in local labor costs of IPFs in the various geographic areas) using the most recent hospital wage data (that is, data from hospital cost reports for the cost reporting period beginning during FY 2011) without any geographic reclassifications, floors, or other adjustments. We propose to apply the FY 2016 IPF PPS wage index to payments beginning October 1, 2015.

We apply the wage index adjustment to the labor-related portion of the Federal rate, which we are proposing to change from 69.294 percent to 74.9 percent in FY 2016. This percentage reflects the labor-related relative importance of the FY 2012-based proposed IPF-specific market basket for FY 2016 (see section III.A.6. of this proposed rule).

c. OMB Bulletins and Proposed Transitional Wage Index

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In the May 2006 IPF PPS final rule for RY 2007 (71 FR 27061 through 27067), we adopted the changes discussed in the Office of Management and Budget (OMB) Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the May 2008 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applies to the hospital wage index used to determine the current IPF PPS wage index and stated that we expect to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721). The OMB bulletins may be accessed online at *http://www.whitehouse.gov/omb/bulletins_default/*.

In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the hospital wage index used to determine the IPF PPS wage index. For the FY 2015 IPF wage index, we used the FY 2014 pre-floor, pre-reclassified hospital wage index to adjust the IPF PPS payments. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/omb/bulletins_default/*. Because the FY 2014 pre-floor, pre-reclassified hospital wage index was finalized prior to the issuance of this Bulletin, the FY 2015 IPF PPS wage index, which was based on the FY 2014 pre-floor, pre-reclassified hospital wage index, did not reflect OMB's new area delineations based on the 2010 Census. According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and Census Bureau data.'' These OMB Bulletin changes are reflected in the FY 2015 pre-floor, pre-reclassified hospital wage index, upon which the FY 2016 IPPS PPS wage index is based. We propose to adopt these new OMB CBSA delineations in the FY 2016 proposed IPF PPS wage index.

We believe that the most current CBSA delineations accurately reflect the local economies and wage levels of the areas where IPFs are located, and we believe that it is important for the IPF PPS to use the latest CBSA delineations available in order to maintain an up-to-date payment system that accurately reflects the reality of population shifts and labor market conditions.

In proposing adoption of these changes for the IPF PPS, it is necessary to identify the new labor market area delineation for each county and facility in the country. For example, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. Because the wage index of urban areas is typically higher than that of rural areas, IPF facilities currently located in rural counties that would become urban, beginning October 1, 2015, would generally experience an increase in their wage index values. We identified 105 counties and 37 IPFs that would move from rural to urban status due to the new CBSA delineations beginning in FY 2016, shown in Table 15.

TABLE 15—FY 2016 RURAL TO URBAN CBSA CROSSWALK

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Baldwin County, Alabama | 1 | RURAL | 0.6963 | 19300 | URBAN | 0.7248 | 4.09 |
| Pickens County, Alabama | 1 | RURAL | 0.6963 | 46220 | URBAN | 0.8337 | 19.73 |
| Cochise County, Arizona | 3 | RURAL | 0.9125 | 43420 | URBAN | 0.8937 | −2.06 |
| Little River County, Arkansas | 4 | RURAL | 0.7311 | 45500 | URBAN | 0.7362 | 0.70 |
| Windham County, Connecticut | 7 | RURAL | 1.1251 | 49340 | URBAN | 1.1493 | 2.15 |
| Sussex County, Delaware | 8 | RURAL | 1.0261 | 41540 | URBAN | 0.9289 | −9.47 |

TABLE 15—FY 2016 RURAL TO URBAN CBSA CROSSWALK—Continued

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Citrus County, Florida | 10 | RURAL | 0.8006 | 26140 | URBAN | 0.7625 | −4.76 |
| Gulf County, Florida | 10 | RURAL | 0.8006 | 37460 | URBAN | 0.7906 | −1.25 |
| Highlands County, Florida | 10 | RURAL | 0.8006 | 42700 | URBAN | 0.7982 | −0.30 |
| Sumter County, Florida | 10 | RURAL | 0.8006 | 45540 | URBAN | 0.8095 | 1.11 |
| Walton County, Florida | 10 | RURAL | 0.8006 | 18880 | URBAN | 0.8156 | 1.87 |
| Lincoln County, Georgia | 11 | RURAL | 0.7425 | 12260 | URBAN | 0.9225 | 24.24 |
| Morgan County, Georgia | 11 | RURAL | 0.7425 | 12060 | URBAN | 0.9369 | 26.18 |
| Peach County, Georgia | 11 | RURAL | 0.7425 | 47580 | URBAN | 0.7542 | 1.58 |
| Pulaski County, Georgia | 11 | RURAL | 0.7425 | 47580 | URBAN | 0.7542 | 1.58 |
| Kalawao County, Hawaii | 12 | RURAL | 1.0741 | 27980 | URBAN | 1.0561 | −1.68 |
| Maui County, Hawaii | 12 | RURAL | 1.0741 | 27980 | URBAN | 1.0561 | −1.68 |
| Butte County, Idaho | 13 | RURAL | 0.7398 | 26820 | URBAN | 0.8933 | 20.75 |
| De Witt County, Illinois | 14 | RURAL | 0.8362 | 14010 | URBAN | 0.9165 | 9.60 |
| Jackson County, Illinois | 14 | RURAL | 0.8362 | 16060 | URBAN | 0.8324 | −0.45 |
| Williamson County, Illinois | 14 | RURAL | 0.8362 | 16060 | URBAN | 0.8324 | −0.45 |
| Scott County, Indiana | 15 | RURAL | 0.8416 | 31140 | URBAN | 0.8605 | 2.25 |
| Union County, Indiana | 15 | RURAL | 0.8416 | 17140 | URBAN | 0.9473 | 12.56 |
| Plymouth County, Iowa | 16 | RURAL | 0.8451 | 43580 | URBAN | 0.8915 | 5.49 |
| Kingman County, Kansas | 17 | RURAL | 0.7806 | 48620 | URBAN | 0.8472 | 8.53 |
| Allen County, Kentucky | 18 | RURAL | 0.7744 | 14540 | URBAN | 0.8410 | 8.60 |
| Butler County, Kentucky | 18 | RURAL | 0.7744 | 14540 | URBAN | 0.8410 | 8.60 |
| Acadia Parish, Louisiana | 19 | RURAL | 0.7580 | 29180 | URBAN | 0.7869 | 3.81 |
| Iberia Parish, Louisiana | 19 | RURAL | 0.7580 | 29180 | URBAN | 0.7869 | 3.81 |
| St. James Parish, Louisiana | 19 | RURAL | 0.7580 | 35380 | URBAN | 0.8821 | 16.37 |
| Tangipahoa Parish, Louisiana | 19 | RURAL | 0.7580 | 25220 | URBAN | 0.9452 | 24.70 |
| Vermilion Parish, Louisiana | 19 | RURAL | 0.7580 | 29180 | URBAN | 0.7869 | 3.81 |
| Webster Parish, Louisiana | 19 | RURAL | 0.7580 | 43340 | URBAN | 0.8325 | 9.83 |
| St. Marys County, Maryland | 21 | RURAL | 0.8554 | 15680 | URBAN | 0.8593 | 0.46 |
| Worcester County, Maryland | 21 | RURAL | 0.8554 | 41540 | URBAN | 0.9289 | 8.59 |
| Midland County, Michigan | 23 | RURAL | 0.8207 | 33220 | URBAN | 0.7935 | −3.31 |
| Montcalm County, Michigan | 23 | RURAL | 0.8207 | 24340 | URBAN | 0.8799 | 7.21 |
| Fillmore County, Minnesota | 24 | RURAL | 0.9124 | 40340 | URBAN | 1.1398 | 24.92 |
| Le Sueur County, Minnesota | 24 | RURAL | 0.9124 | 33460 | URBAN | 1.1196 | 22.71 |
| Mille Lacs County, Minnesota | 24 | RURAL | 0.9124 | 33460 | URBAN | 1.1196 | 22.71 |
| Sibley County, Minnesota | 24 | RURAL | 0.9124 | 33460 | URBAN | 1.1196 | 22.71 |
| Benton County, Mississippi | 25 | RURAL | 0.7589 | 32820 | URBAN | 0.8991 | 18.47 |
| Yazoo County, Mississippi | 25 | RURAL | 0.7589 | 27140 | URBAN | 0.7891 | 3.98 |
| Golden Valley County, Montana | 27 | RURAL | 0.9024 | 13740 | URBAN | 0.8686 | −3.75 |
| Hall County, Nebraska | 28 | RURAL | 0.8924 | 24260 | URBAN | 0.9219 | 3.31 |
| Hamilton County, Nebraska | 28 | RURAL | 0.8924 | 24260 | URBAN | 0.9219 | 3.31 |
| Howard County, Nebraska | 28 | RURAL | 0.8924 | 24260 | URBAN | 0.9219 | 3.31 |
| Merrick County, Nebraska | 28 | RURAL | 0.8924 | 24260 | URBAN | 0.9219 | 3.31 |
| Jefferson County, New York | 33 | RURAL | 0.8208 | 48060 | URBAN | 0.8386 | 2.17 |
| Yates County, New York | 33 | RURAL | 0.8208 | 40380 | URBAN | 0.8750 | 6.60 |
| Craven County, North Carolina | 34 | RURAL | 0.7995 | 35100 | URBAN | 0.8994 | 12.50 |
| Davidson County, North Carolina | 34 | RURAL | 0.7995 | 49180 | URBAN | 0.8679 | 8.56 |
| Gates County, North Carolina | 34 | RURAL | 0.7995 | 47260 | URBAN | 0.9223 | 15.36 |
| Iredell County, North Carolina | 34 | RURAL | 0.7995 | 16740 | URBAN | 0.9073 | 13.48 |
| Jones County, North Carolina | 34 | RURAL | 0.7995 | 35100 | URBAN | 0.8994 | 12.50 |
| Lincoln County, North Carolina | 34 | RURAL | 0.7995 | 16740 | URBAN | 0.9073 | 13.48 |
| Pamlico County, North Carolina | 34 | RURAL | 0.7995 | 35100 | URBAN | 0.8994 | 12.50 |
| Rowan County, North Carolina | 34 | RURAL | 0.7995 | 16740 | URBAN | 0.9073 | 13.48 |
| Oliver County, North Dakota | 35 | RURAL | 0.7099 | 13900 | URBAN | 0.7216 | 1.65 |
| Sioux County, North Dakota | 35 | RURAL | 0.7099 | 13900 | URBAN | 0.7216 | 1.65 |
| Hocking County, Ohio | 36 | RURAL | 0.8329 | 18140 | URBAN | 0.9539 | 14.53 |
| Perry County, Ohio | 36 | RURAL | 0.8329 | 18140 | URBAN | 0.9539 | 14.53 |
| Cotton County, Oklahoma | 37 | RURAL | 0.7799 | 30020 | URBAN | 0.7918 | 1.53 |
| Josephine County, Oregon | 38 | RURAL | 1.0083 | 24420 | URBAN | 1.0086 | 0.03 |
| Linn County, Oregon | 38 | RURAL | 1.0083 | 10540 | URBAN | 1.0879 | 7.89 |
| Adams County, Pennsylvania | 39 | RURAL | 0.8719 | 23900 | URBAN | 1.0104 | 15.88 |
| Columbia County, Pennsylvania | 39 | RURAL | 0.8719 | 14100 | URBAN | 0.9347 | 7.20 |
| Franklin County, Pennsylvania | 39 | RURAL | 0.8719 | 16540 | URBAN | 1.0957 | 25.67 |
| Monroe County, Pennsylvania | 39 | RURAL | 0.8719 | 20700 | URBAN | 0.9372 | 7.49 |
| Montour County, Pennsylvania | 39 | RURAL | 0.8719 | 14100 | URBAN | 0.9347 | 7.20 |
| Utuado Municipio, Puerto Rico | 40 | RURAL | 0.4047 | 10380 | URBAN | 0.3586 | −11.39 |
| Beaufort County, South Carolina | 42 | RURAL | 0.8374 | 25940 | URBAN | 0.8708 | 3.99 |
| Chester County, South Carolina | 42 | RURAL | 0.8374 | 16740 | URBAN | 0.9073 | 8.35 |
| Jasper County, South Carolina | 42 | RURAL | 0.8374 | 25940 | URBAN | 0.8708 | 3.99 |

TABLE 15—FY 2016 RURAL TO URBAN CBSA CROSSWALK—Continued

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Lancaster County, South Carolina | 42 | RURAL | 0.8374 | 16740 | URBAN | 0.9073 | 8.35 |
| Union County, South Carolina | 42 | RURAL | 0.8374 | 43900 | URBAN | 0.8277 | −1.16 |
| Custer County, South Dakota | 43 | RURAL | 0.8312 | 39660 | URBAN | 0.8989 | 8.14 |
| Campbell County, Tennessee | 44 | RURAL | 0.7365 | 28940 | URBAN | 0.7015 | −4.75 |
| Crockett County, Tennessee | 44 | RURAL | 0.7365 | 27180 | URBAN | 0.7747 | 5.19 |
| Maury County, Tennessee | 44 | RURAL | 0.7365 | 34980 | URBAN | 0.8969 | 21.78 |
| Morgan County, Tennessee | 44 | RURAL | 0.7365 | 28940 | URBAN | 0.7015 | −4.75 |
| Roane County, Tennessee | 44 | RURAL | 0.7365 | 28940 | URBAN | 0.7015 | −4.75 |
| Falls County, Texas | 45 | RURAL | 0.7855 | 47380 | URBAN | 0.8137 | 3.59 |
| Hood County, Texas | 45 | RURAL | 0.7855 | 23104 | URBAN | 0.9386 | 19.49 |
| Hudspeth County, Texas | 45 | RURAL | 0.7855 | 21340 | URBAN | 0.8139 | 3.62 |
| Lynn County, Texas | 45 | RURAL | 0.7855 | 31180 | URBAN | 0.8830 | 12.41 |
| Martin County, Texas | 45 | RURAL | 0.7855 | 33260 | URBAN | 0.8940 | 13.81 |
| Newton County, Texas | 45 | RURAL | 0.7855 | 13140 | URBAN | 0.8508 | 8.31 |
| Oldham County, Texas | 45 | RURAL | 0.7855 | 11100 | URBAN | 0.8277 | 5.37 |
| Somervell County, Texas | 45 | RURAL | 0.7855 | 23104 | URBAN | 0.9386 | 19.49 |
| Box Elder County, Utah | 46 | RURAL | 0.8891 | 36260 | URBAN | 0.9225 | 3.76 |
| Augusta County, Virginia | 49 | RURAL | 0.7674 | 44420 | URBAN | 0.8326 | 8.50 |
| Buckingham County, Virginia | 49 | RURAL | 0.7674 | 16820 | URBAN | 0.9053 | 17.97 |
| Culpeper County, Virginia | 49 | RURAL | 0.7674 | 47894 | URBAN | 1.0403 | 35.56 |
| Floyd County, Virginia | 49 | RURAL | 0.7674 | 13980 | URBAN | 0.8473 | 10.41 |
| Rappahannock County, Virginia | 49 | RURAL | 0.7674 | 47894 | URBAN | 1.0403 | 35.56 |
| Staunton City County, Virginia | 49 | RURAL | 0.7674 | 44420 | URBAN | 0.8326 | 8.50 |
| Waynesboro City County, Virginia | 49 | RURAL | 0.7674 | 44420 | URBAN | 0.8326 | 8.50 |
| Columbia County, Washington | 50 | RURAL | 1.0892 | 47460 | URBAN | 1.0934 | 0.39 |
| Pend Oreille County, Washington | 50 | RURAL | 1.0892 | 44060 | URBAN | 1.1425 | 4.89 |
| Stevens County, Washington | 50 | RURAL | 1.0892 | 44060 | URBAN | 1.1425 | 4.89 |
| Walla Walla County, Washington | 50 | RURAL | 1.0892 | 47460 | URBAN | 1.0934 | 0.39 |
| Fayette County, West Virginia | 51 | RURAL | 0.7410 | 13220 | URBAN | 0.8024 | 8.29 |
| Raleigh County, West Virginia | 51 | RURAL | 0.7410 | 13220 | URBAN | 0.8024 | 8.29 |
| Green County, Wisconsin | 52 | RURAL | 0.9041 | 31540 | URBAN | 1.1130 | 23.11 |

The wage index values of rural areas are typically lower than that of urban areas. Therefore, IPFs located in a county that is currently designated as urban under the IPF PPS wage index that would become rural when we would adopt the new CBSA delineations may experience a decrease in their wage index values. We identified 37 counties and 3 IPFs that would move from urban to rural status due to the new CBSA delineations beginning in FY 2016. Table 16 shows the CBSA delineations and the urban wage index values for FY 2015 based on existing CBSA delineations, compared with the proposed CBSA delineations and wage index values for FY 2016 based on the new OMB CBSA delineations. Table 16 also shows the percentage change in these values for those counties that would change from urban to rural, beginning in FY 2016, when we would adopt the new CBSA delineations.

TABLE 16—FY 2016 URBAN TO RURAL CBSA CROSSWALK

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Greene County, Alabama | 46220 | URBAN | 0.8387 | 1 | RURAL | 0.6914 | −17.56 |
| Franklin County, Arkansas | 22900 | URBAN | 0.7593 | 4 | RURAL | 0.7311 | −3.71 |
| Power County, Idaho | 38540 | URBAN | 0.9672 | 13 | RURAL | 0.7398 | −23.51 |
| Franklin County, Indiana | 17140 | URBAN | 0.9473 | 15 | RURAL | 0.8416 | −11.16 |
| Gibson County, Indiana | 21780 | URBAN | 0.8537 | 15 | RURAL | 0.8416 | −1.42 |
| Greene County, Indiana | 14020 | URBAN | 0.9062 | 15 | RURAL | 0.8416 | −7.13 |
| Tipton County, Indiana | 29020 | URBAN | 0.8990 | 15 | RURAL | 0.8416 | −6.38 |
| Franklin County, Kansas | 28140 | URBAN | 0.9419 | 17 | RURAL | 0.7779 | −17.41 |
| Geary County, Kansas | 31740 | URBAN | 0.8406 | 17 | RURAL | 0.7779 | −7.46 |
| Nelson County, Kentucky | 31140 | URBAN | 0.8593 | 18 | RURAL | 0.7748 | −9.83 |
| Webster County, Kentucky | 21780 | URBAN | 0.8537 | 18 | RURAL | 0.7748 | −9.24 |
| Franklin County, Massachusetts | 44140 | URBAN | 1.0271 | 22 | RURAL | 1.1553 | 12.48 |
| Ionia County, Michigan | 24340 | URBAN | 0.8965 | 23 | RURAL | 0.8288 | −7.55 |
| Newaygo County, Michigan | 24340 | URBAN | 0.8965 | 23 | RURAL | 0.8288 | −7.55 |
| George County, Mississippi | 37700 | URBAN | 0.7396 | 25 | RURAL | 0.7570 | 2.35 |
| Stone County, Mississippi | 25060 | URBAN | 0.8179 | 25 | RURAL | 0.7570 | −7.45 |

TABLE 16—FY 2016 URBAN TO RURAL CBSA CROSSWALK—Continued

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Crawford County, Missouri | 41180 | URBAN | 0.9366 | 26 | RURAL | 0.7725 | −17.52 |
| Howard County, Missouri | 17860 | URBAN | 0.8319 | 26 | RURAL | 0.7725 | −7.14 |
| Washington County, Missouri | 41180 | URBAN | 0.9366 | 26 | RURAL | 0.7725 | −17.52 |
| Anson County, North Carolina | 16740 | URBAN | 0.9230 | 34 | RURAL | 0.7899 | −14.42 |
| Greene County, North Carolina | 24780 | URBAN | 0.9371 | 34 | RURAL | 0.7899 | −15.71 |
| Erie County, Ohio | 41780 | URBAN | 0.7784 | 36 | RURAL | 0.8348 | 7.25 |
| Ottawa County, Ohio | 45780 | URBAN | 0.9129 | 36 | RURAL | 0.8348 | −8.56 |
| Preble County, Ohio | 19380 | URBAN | 0.8938 | 36 | RURAL | 0.8348 | −6.60 |
| Washington County, Ohio | 37620 | URBAN | 0.8186 | 36 | RURAL | 0.8348 | 1.98 |
| Stewart County, Tennessee | 17300 | URBAN | 0.7526 | 44 | RURAL | 0.7277 | −3.31 |
| Calhoun County, Texas | 47020 | URBAN | 0.8473 | 45 | RURAL | 0.7847 | −7.39 |
| Delta County, Texas | 19124 | URBAN | 0.9703 | 45 | RURAL | 0.7847 | −19.13 |
| San Jacinto County, Texas | 26420 | URBAN | 0.9734 | 45 | RURAL | 0.7847 | −19.39 |
| Summit County, Utah | 41620 | URBAN | 0.9512 | 46 | RURAL | 0.9005 | −5.33 |
| Cumberland County, Virginia | 40060 | URBAN | 0.9625 | 49 | RURAL | 0.7554 | −21.52 |
| Danville City County, Virginia | 19260 | URBAN | 0.7963 | 49 | RURAL | 0.7554 | −5.14 |
| King And Queen County, Virginia | 40060 | URBAN | 0.9625 | 49 | RURAL | 0.7554 | −21.52 |
| Louisa County, Virginia | 40060 | URBAN | 0.9625 | 49 | RURAL | 0.7554 | −21.52 |
| Pittsylvania County, Virginia | 19260 | URBAN | 0.7963 | 49 | RURAL | 0.7554 | −5.14 |
| Surry County, Virginia | 47260 | URBAN | 0.9223 | 49 | RURAL | 0.7554 | −18.10 |
| Morgan County, West Virginia | 25180 | URBAN | 0.9080 | 51 | RURAL | 0.7274 | −19.89 |
| Pleasants County, West Virginia | 37620 | URBAN | 0.8186 | 51 | RURAL | 0.7274 | −11.14 |

We note that IPFs in some urban CBSAs would experience a change in their wage index values even though they remain urban because an urban CBSA's boundaries and/or the counties included in that CBSA could change. Table 17 shows those counties that would experience a change in their wage index value in FY 2016 due to the new OMB CBSAs. Table 17 shows the urban CBSA delineations and wage index values for FY 2015 based on existing CBSA delineations, compared with the urban CBSA delineations and wage index values for FY 2016 based on the new OMB delineations, and the percentage change in these values, for counties that would remain urban even though the CBSA boundaries and/or counties included in that CBSA would change.

TABLE 17—FY 2015 URBAN TO A DIFFERENT FY 2016 URBAN CBSA CROSSWALK

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Flagler County, Florida | 37380 | URBAN | 0.8462 | 19660 | URBAN | 0.8376 | −1.02 |
| De Kalb County, Illinois | 16974 | URBAN | 1.0412 | 20994 | URBAN | 1.0299 | −1.09 |
| Kane County, Illinois | 16974 | URBAN | 1.0412 | 20994 | URBAN | 1.0299 | −1.09 |
| Madison County, Indiana | 11300 | URBAN | 1.0078 | 26900 | URBAN | 1.0133 | 0.55 |
| Meade County, Kentucky | 31140 | URBAN | 0.8593 | 21060 | URBAN | 0.7701 | −10.38 |
| Essex County, Massachusetts | 37764 | URBAN | 1.0769 | 15764 | URBAN | 1.1159 | 3.62 |
| Ottawa County, Michigan | 26100 | URBAN | 0.8136 | 24340 | URBAN | 0.8799 | 8.15 |
| Jackson County, Mississippi | 37700 | URBAN | 0.7396 | 25060 | URBAN | 0.7896 | 6.76 |
| Bergen County, New Jersey | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Hudson County, New Jersey | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Middlesex County, New Jersey | 20764 | URBAN | 1.0989 | 35614 | URBAN | 1.2837 | 16.82 |
| Monmouth County, New Jersey | 20764 | URBAN | 1.0989 | 35614 | URBAN | 1.2837 | 16.82 |
| Ocean County, New Jersey | 20764 | URBAN | 1.0989 | 35614 | URBAN | 1.2837 | 16.82 |
| Passaic County, New Jersey | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Somerset County, New Jersey | 20764 | URBAN | 1.0989 | 35084 | URBAN | 1.1233 | 2.22 |
| Bronx County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Dutchess County, New York | 39100 | URBAN | 1.1533 | 20524 | URBAN | 1.1345 | −1.63 |
| Kings County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| New York County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Orange County, New York | 39100 | URBAN | 1.1533 | 35614 | URBAN | 1.2837 | 11.31 |
| Putnam County, New York | 35644 | URBAN | 1.3110 | 20524 | URBAN | 1.1345 | −13.46 |
| Queens County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Richmond County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Rockland County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Westchester County, New York | 35644 | URBAN | 1.3110 | 35614 | URBAN | 1.2837 | −2.08 |
| Brunswick County, North Carolina | 48900 | URBAN | 0.8867 | 34820 | URBAN | 0.8620 | −2.79 |
| Bucks County, Pennsylvania | 37964 | URBAN | 1.0837 | 33874 | URBAN | 1.0157 | −6.27 |

TABLE 17—FY 2015 URBAN TO A DIFFERENT FY 2016 URBAN CBSA CROSSWALK—Continued

| County name | FY 2014 CBSA Delineations/FY 2015 data | | | FY 2015 CBSA Delineations/FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| Chester County, Pennsylvania | 37964 | URBAN | 1.0837 | 33874 | URBAN | 1.0157 | −6.27 |
| Montgomery County, Pennsylvania | 37964 | URBAN | 1.0837 | 33874 | URBAN | 1.0157 | −6.27 |
| Arecibo Municipio, Puerto Rico | 41980 | URBAN | 0.4449 | 11640 | URBAN | 0.4213 | −5.30 |
| Camuy Municipio, Puerto Rico | 41980 | URBAN | 0.4449 | 11640 | URBAN | 0.4213 | −5.30 |
| Ceiba Municipio, Puerto Rico | 21940 | URBAN | 0.3669 | 41980 | URBAN | 0.4438 | 20.96 |
| Fajardo Municipio, Puerto Rico | 21940 | URBAN | 0.3669 | 41980 | URBAN | 0.4438 | 20.96 |
| Guanica Municipio, Puerto Rico | 49500 | URBAN | 0.3375 | 38660 | URBAN | 0.4154 | 23.08 |
| Guayanilla Municipio, Puerto Rico | 49500 | URBAN | 0.3375 | 38660 | URBAN | 0.4154 | 23.08 |
| Hatillo Municipio, Puerto Rico | 41980 | URBAN | 0.4449 | 11640 | URBAN | 0.4213 | −5.30 |
| Luquillo Municipio, Puerto Rico | 21940 | URBAN | 0.3669 | 41980 | URBAN | 0.4438 | 20.96 |
| Penuelas Municipio, Puerto Rico | 49500 | URBAN | 0.3375 | 38660 | URBAN | 0.4154 | 23.08 |
| Quebradillas Municipio, Puerto Rico | 41980 | URBAN | 0.4449 | 11640 | URBAN | 0.4213 | −5.30 |
| Yauco Municipio, Puerto Rico | 49500 | URBAN | 0.3375 | 38660 | URBAN | 0.4154 | 23.08 |
| Anderson County, South Carolina | 11340 | URBAN | 0.8744 | 24860 | URBAN | 0.9161 | 4.77 |
| Grainger County, Tennessee | 34100 | URBAN | 0.6983 | 28940 | URBAN | 0.7015 | 0.46 |
| Lincoln County, West Virginia | 16620 | URBAN | 0.7988 | 26580 | URBAN | 0.8846 | 10.74 |
| Putnam County, West Virginia | 16620 | URBAN | 0.7988 | 26580 | URBAN | 0.8846 | 10.74 |

Likewise, IPFs currently located in a rural area may remain rural under the new CBSA delineations but experience a change in their rural wage index value due to implementation of the new CBSA delineations. Table 18 shows the FY 2015 CBSA delineations and rural statewide wage index values, compared with the FY 2016 CBSA delineations and rural statewide wage index values, and the percentage change in these values, for those rural areas that would change.

TABLE 18—FY 2016 CHANGES TO THE STATEWIDE RURAL WAGE INDEX CROSSWALK

| County name | FY 2014 CBSA Delineations/ FY 2015 data | | | FY 2015 CBSA Delineations/ FY 2015 data | | | Change in value (percent) |
|---|---|---|---|---|---|---|---|
| | CBSA | Urban/ Rural | Wage index | CBSA | Urban/ Rural | Wage index | |
| ALABAMA | 1 | RURAL | 0.6963 | 1 | RURAL | 0.6914 | −0.70 |
| ARIZONA | 3 | RURAL | 0.9125 | 3 | RURAL | 0.9219 | 1.03 |
| CONNECTICUT | 7 | RURAL | 1.1251 | 7 | RURAL | 1.1295 | 0.39 |
| FLORIDA | 10 | RURAL | 0.8006 | 10 | RURAL | 0.8371 | 4.56 |
| GEORGIA | 11 | RURAL | 0.7425 | 11 | RURAL | 0.7439 | 0.19 |
| HAWAII | 12 | RURAL | 1.0741 | 12 | RURAL | 1.0872 | 1.22 |
| ILLINOIS | 14 | RURAL | 0.8362 | 14 | RURAL | 0.8369 | 0.08 |
| KANSAS | 17 | RURAL | 0.7806 | 17 | RURAL | 0.7779 | −0.35 |
| KENTUCKY | 18 | RURAL | 0.7744 | 18 | RURAL | 0.7748 | 0.05 |
| LOUISIANA | 19 | RURAL | 0.7580 | 19 | RURAL | 0.7108 | −6.23 |
| MARYLAND | 21 | RURAL | 0.8554 | 21 | RURAL | 0.8746 | 2.24 |
| MASSACHUSETTS | 22 | RURAL | 1.3920 | 22 | RURAL | 1.1553 | −17.00 |
| MICHIGAN | 23 | RURAL | 0.8207 | 23 | RURAL | 0.8288 | 0.99 |
| MISSISSIPPI | 25 | RURAL | 0.7589 | 25 | RURAL | 0.7570 | −0.25 |
| NEBRASKA | 28 | RURAL | 0.8924 | 28 | RURAL | 0.8877 | −0.53 |
| NEW YORK | 33 | RURAL | 0.8208 | 33 | RURAL | 0.8192 | −0.19 |
| NORTH CAROLINA | 34 | RURAL | 0.7995 | 34 | RURAL | 0.7899 | −1.20 |
| OHIO | 36 | RURAL | 0.8329 | 36 | RURAL | 0.8348 | 0.23 |
| OREGON | 38 | RURAL | 1.0083 | 38 | RURAL | 0.9949 | −1.33 |
| PENNSYLVANIA | 39 | RURAL | 0.8719 | 39 | RURAL | 0.8083 | −7.29 |
| SOUTH CAROLINA | 42 | RURAL | 0.8374 | 42 | RURAL | 0.8370 | −0.05 |
| TENNESSEE | 44 | RURAL | 0.7365 | 44 | RURAL | 0.7277 | −1.19 |
| TEXAS | 45 | RURAL | 0.7855 | 45 | RURAL | 0.7847 | −0.10 |
| UTAH | 46 | RURAL | 0.8891 | 46 | RURAL | 0.9005 | 1.28 |
| VIRGINIA | 49 | RURAL | 0.7674 | 49 | RURAL | 0.7554 | −1.56 |
| WASHINGTON | 50 | RURAL | 1.0892 | 50 | RURAL | 1.0877 | −0.14 |
| WEST VIRGINIA | 51 | RURAL | 0.7410 | 51 | RURAL | 0.7274 | −1.84 |
| WISCONSIN | 52 | RURAL | 0.9041 | 52 | RURAL | 0.9087 | 0.51 |

While we believe that the new CBSA delineations would result in wage index values that are more representative of the actual costs of labor in a given area, we also recognize that use of the new CBSA delineations would result in reduced payments to some IPFs and increased payments to other IPFs, due to changes in wage index values.

Approximately 23.4 percent of IPFs would experience a decrease in wage index values due to CBSA changes, while 12.4 percent of IPFs would experience an increase in wage index values due to CBSA changes. The remaining 64.1 percent of IPFs would experience no change in their wage index values (these percentages do not sum to 100.0 percent due to rounding). While the wage index CBSA changes would be implemented in a budget-neutral fashion, the distributional effects of these CBSA changes appear to affect rural IPFs in particular; column 5 in Table 26 in section VII. of this proposed rule shows that rural providers overall are anticipated to experience payment reductions of 0.2 percent, with for-profit rural psychiatric hospitals anticipated to experience the greatest reduction of 0.6 percent. We believe that it would be appropriate to provide for a transition period to mitigate any negative impacts on facilities that experience reduced payments as a result of our adopting the new OMB CBSA delineations. Therefore, we propose to implement these CBSA changes using a 1-year transition with a blended wage index for all providers. For FY 2016, the wage index for each provider would consist of a blend of 50 percent of the FY 2016 IPF wage index using the current OMB delineations and 50 percent of the FY 2016 IPF wage index using the new OMB delineations. This results in an average of the 2 values. We propose that the FY 2017 IPF PPS wage index and subsequent IPF PPS wage indices would be based solely on the new OMB CBSA delineations. We believe a 1-year transition strikes an appropriate balance between ensuring that IPF PPS payments are as accurate and stable as possible while giving IPFs time to adjust to the new CBSA delineations. The proposed FY 2016 IPF PPS Transitional wage index is located on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html*.

d. Adjustment for Rural Location and Proposal to Phase Out the Rural Adjustment for IPFs Losing Their Rural Adjustment Due to CBSA Changes

In the November 2004 IPF PPS final rule, we provided a 17 percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. For FY 2016, we propose to continue to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). A complete discussion of the adjustment for rural locations appears in the November 2004 IPF PPS final rule (69 FR 66954).

As noted in section III.D.1.c. of this proposed rule, we are proposing to adopt OMB updates to CBSA delineations. Adoption of the updated CBSAs would change the status of 37 IPF providers currently designated as ''rural'' to ''urban'' for FY 2016 and subsequent fiscal years. As such, these 37 newly-urban providers would no longer receive the 17 percent rural adjustment.

While 34 of these 37 rural IPFs that would be designated as urban under the new CBSA delineations would experience an increase in their wage index value, all 37 of these IPFs would lose the 17 percent rural adjustment. Consistent with the transition policy adopted for Inpatient Rehabilitation Facilities (IRFs) in FY 2006 (70 FR 47923 through 47927), we considered the appropriateness of applying a 3-year phase-out of the rural adjustment for IPFs located in rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these IPFs. We believe that a phase-out of the rural adjustment transition period for these 37 IPFs specifically is appropriate because we expect these IPFs would experience a steeper and more abrupt reduction in their payments compared to other IPFs.

Therefore, in addition to the 2-year wage index transition policy noted above, we are proposing a budget-neutral 3-year phase-out of the rural adjustment for existing FY 2015 rural IPFs that would become urban in FY 2016 and that experience a loss in payments due to changes from the new CBSA delineations. Accordingly, the incremental steps needed to reduce the impact of the loss of the FY 2015 rural adjustment of 17 percent would be taken over FYs 2016, 2017 and 2018. This policy would allow rural IPFs that would be classified as urban in FY 2016 to receive two-thirds of the 2015 rural adjustment for FY 2016, as well as the blended wage index. For FY 2017, these IPFs would receive the full FY 2017 wage index and one-third of the FY 2015 rural adjustment. For FY 2018, these IPFs would receive the full FY 2018 wage index without a rural adjustment. We believe a 3-year budget-neutral phase-out of the rural adjustment for IPFs that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural adjustment for existing FY 2015 rural IPFs. The purpose of the gradual phase-out of the rural adjustment for these providers is to alleviate the significant payment implications for existing rural IPFs that may need time to adjust to the loss of their FY 2015 rural payment adjustment or that experience a reduction in payments solely because of this re-designation. As stated, this policy is specifically for rural IPFs that become urban in FY 2016. We are not implementing a transition policy for urban IPFs that become rural in FY 2016 because these IPFs will receive the full rural adjustment of 17 percent beginning October 1, 2015.

For the reasons discussed, we are proposing to implement a 3-year budget-neutral phase-out of the rural adjustment for the IPFs that during FY 2015 were designated as rural and for FY 2016 are designated as urban under the new CBSA system. This is in addition to our proposed implementation of a 2-year blended wage index for all IPFs. We believe that the incremental reduction of the FY 2015 rural adjustment would be appropriate to mitigate a significant reduction in payment. We considered alternative timeframes for phasing out the rural adjustment for IPFs which would transition from rural to urban status in FY 2016, but believe that a 3-year budget-neutral phase-out of the rural adjustment would appropriately mitigate the adverse payment impacts for existing FY 2015 rural IPFs that will be designated as urban IPFs in FY 2016, while also ensuring that payment rates for these providers are set accurately and appropriately. We invite public comment on this proposed policy.

e. Budget Neutrality Adjustment

Changes to the wage index are made in a budget-neutral manner so that updates do not increase expenditures. Therefore, for FY 2016, we propose to continue to apply a budget-neutrality adjustment in accordance with our existing budget-neutrality policy. This policy requires us to estimate the total amount of IPF PPS payments for FY 2016 using the labor-related share and the wage indices from FY 2015 divided by the total estimated IPF PPS payments for FY 2016 using the labor-related share and wage indices from FY 2016. The estimated payments are based on FY 2014 IPF claims, inflated to the appropriate FY. This quotient is the wage index budget-neutrality factor, and it is applied in the update of the Federal per diem base rate for FY 2016 in addition to the market basket described in section III.A. of this proposed rule.

The proposed wage index budget-neutrality factor for FY 2016 is 1.0041.

2. Teaching Adjustment

In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census (ADC).

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's ''teaching variable,'' which is one plus the ratio of the number of FTE residents training in the IPF (subject to limitations described below) to the IPF's ADC.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a ''base year'' and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (that is, the publication date of the IPF PPS final rule). A complete discussion on the temporary adjustment to the FTE cap to reflect residents added due to hospital closure and by residency program appears in the January 27, 2011 IPF PPS proposed rule (76 FR 5018 through 5020) and the May 6, 2011 IPF PPS final rule (76 R 26453 through 26456).

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS final rule (69 FR 66954 through 66957) and the May 2008 IPF PPS notice (73 FR 25721). As with other adjustment factors derived through the regression analysis, we do not plan to rerun the teaching adjustment factors in the regression analysis until we more fully analyze IPF PPS data. Therefore, in this proposed rule, for FY 2016, we propose to continue to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

3. Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the county in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare PPSs (for example, the IPPS and LTCH PPS) adopted a cost of living adjustment (COLA) to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii would improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA for IPFs located in Alaska and Hawaii is made by multiplying the nonlabor-related portion of the Federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors are published on the Office of Personnel Management (OPM) Web site (*http://www.opm.gov/oca/cola/rates.asp*).

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- Rest of the State of Alaska.

As stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the OPM. However, sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Pub. L. 111–84, locality pay is being phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA factors in the January 2011 IPF PPS proposed rule (76 FR 4998), we inadvertently selected the FY 2010 COLA rates which had been reduced to account for the phase-in of locality pay. We did not intend to propose the reduced COLA rates because that would have understated the adjustment. Since the 2009 COLA rates did not reflect the phase-in of locality pay, we finalized the FY 2009 COLA rates for RY 2010 through RY 2014.

In the FY 2013 IPPS/LTCH final rule (77 FR 53700 through 53701), CMS established a methodology for FY 2014 to update the COLA factors for Alaska and Hawaii. Under that methodology, we use a comparison of the growth in the Consumer Price Indices (CPIs) in Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the overall CPI as published by the Bureau of Labor Statistics (BLS) to update the COLA factors for all areas in Alaska and Hawaii, respectively. As discussed in the FY 2013 IPPS/LTCH proposed rule (77 FR 28145), because BLS publishes CPI data for only Anchorage, Alaska and Honolulu, Hawaii, our methodology for updating the COLA factors uses a comparison of the growth in the CPIs for those cities relative to the growth in the overall CPI to update the COLA factors

for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are generally appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

The CPIs for ''All Items'' that BLS publishes for Anchorage, Alaska, Honolulu, Hawaii, and for the average U.S. city are based on a different mix of commodities and services than is reflected in the nonlabor-related share of the IPPS market basket. As such, under the methodology we established to update the COLA factors, we calculated a ''reweighted CPI'' using the CPI for commodities and the CPI for services for each of the geographic areas to mirror the composition of the IPPS market basket nonlabor-related share. The current composition of BLS' CPI for ''All Items'' for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the nonlabor-related share of the IPPS market basket is comprised of 60 percent commodities and 40 percent services. Therefore, under the methodology established for FY 2014 in the FY 2013 IPPS/LTCH PPS final rule, we created reweighted indexes for Anchorage, Alaska, Honolulu, Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and applying the approximate 60/40 weights from the IPPS market basket. This approach is appropriate because we would continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor.

Under the COLA factor update methodology established in the FY 2014 IPPS/LTCH final rule, we adjust payments made to hospitals located in Alaska and Hawaii by incorporating a 25-percent cap on the CPI-updated COLA factors. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and since at least 1984, we have exercised our discretionary authority to adjust Alaska and Hawaii payments by incorporating this cap. In keeping with this historical policy, we would continue to use such a cap, as our proposal is based on OPM's COLA factors. We believe this approach is appropriate because our CPI-updated COLA factors use the 2009 OPM COLA factors as a basis.

In FY 2015 IPF PPS rulemaking, we adopted the same methodology for the COLA factors applied under the IPPS because IPFs are hospitals with a similar mix of commodities and services. We think it is appropriate to have a consistent policy approach with that of other hospitals in Alaska and Hawaii. Therefore, in the FY 2015 IPF PPS final rule, we adopted the cost of living adjustment factors shown in the Addendum for IPFs located in Alaska and Hawaii. Under IPPS COLA policy, the COLA updates are determined every four years, when the IPPS market basket is rebased. Since the IPPS COLA factors were last updated in FY 2014, they are not scheduled to be updated again until FY 2018. As such, we propose to continue using the existing IPF PPS COLA factors in effect in FY 2015 for FY 2016. The IPF PPS COLA factors for FY 2016 are shown in the Addendum of this proposed rule.

4. Proposed Adjustment for IPFs With a Qualifying Emergency Department (ED)

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a freestanding psychiatric hospital with a qualifying ED or a distinct part psychiatric unit of an acute care hospital or a CAH, for preadmission services otherwise payable under the Medicare Outpatient Prospective Payment System (OPPS), furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)), and the overhead cost of maintaining the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception described below), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. That is, IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each stay. If an IPF does not have a qualifying ED, it receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described below. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an acute care hospital or CAH and admitted to the same hospital's or CAH's psychiatric unit. We clarified in the November 2004 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the acute care hospital or through the reasonable cost payment made to the CAH.

Therefore, when patients are discharged from an acute care hospital or CAH and admitted to the same hospital or CAH's psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF.

For FY 2016, we are proposing to continue to retain the 1.31 adjustment factor for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factor appears in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the May 2006 IPF PPS final rule (71 FR 27070 through 27072).

*E. Other Proposed Payment Adjustments and Policies*

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require more costly care and, therefore, reduce the incentives for IPFs to under-serve these patients.

We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. We established the 80 percent and 60 percent loss sharing

ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments.

After establishing the loss sharing ratios, we determined the current FY 2015 fixed dollar loss threshold amount through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total projected IPF PPS payments.

2. Proposed Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we propose to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases.

Based on an analysis of the latest available data (that is, FY 2014 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount in order to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. To update the IPF outlier threshold amount for FY 2016, we propose to use FY 2014 claims data and the same methodology that we used to set the initial outlier threshold amount in the May 2006 IPF PPS final rule (71 FR 27072 and 27073), which is also the same methodology that we used to update the outlier threshold amounts for years 2008 through 2015. Based on an analysis of this updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.3 percent in FY 2015. Therefore, we propose to update the outlier threshold amount to $9,825 to maintain estimated outlier payments at approximately 2 percent of total estimated aggregate IPF payments for FY 2016.

3. Proposed Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. In order to establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In the June 2003 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for acute care hospitals because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs in order to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule (69 FR 66961), because we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the November 2004 IPF PPS final rule: We calculated 2 national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas. We computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the CY 2015 Provider Specific File.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2016 is 1.9041 for rural IPFs, and 1.6881 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- IPFs whose overall CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for which the MAC obtains inaccurate or incomplete data with which to calculate a CCR.

We are not proposing to make any changes to the application of the national CCRs or to the procedures for updating the CCR ceilings in FY 2016. However, we are proposing to update the FY 2016 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS Provider Specific File. Specifically, for FY 2016, and to be used in each of the 3 situations listed above, using the most recent CCRs entered in the CY 2015 Provider Specific File we estimate the national median CCR of 0.6210 for rural IPFs and the national median CCR of 0.4675 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations.

A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

## IV. Other Payment Policy Issues

### *A. ICD–10–CM and ICD–10–PCS Implementation*

We remind IPF providers that CMS is implementing the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) as the HIPAA designated code set for reporting diseases, injuries, impairments, other health related problems, their manifestations, and causes of injury as of October 1, 2015. Below is a brief history of key activities leading to the October 1, 2015 implementation date.

In the Standards for Electronic Transactions final rule, published in the **Federal Register** on August 17, 2000 (65 FR 50312), the Department adopted the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) as the HIPAA designated code set for reporting diseases, injuries, impairments, other health related problems, their manifestations, and causes of injury. Therefore, on January 1, 2005 when the IPF PPS began, we used ICD–9–CM as the designated code set for the IPF PPS. IPF claims with a principal diagnosis included in Chapter Five of the ICD–9–CM are paid the Federal per diem base rate and all other applicable adjustments, including any applicable DRG adjustment.

Together with the rest of the healthcare industry, CMS was scheduled to implement the 10th revision of the ICD coding scheme, that is, ICD–10–CM, on October 1, 2014. Hence, in the FY 2014 IPF PPS final rule (78 FR 46741–46742), we finalized a policy that ICD–10–CM codes will be used in IPF PPS.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA)

(Pub. L. 113–93) was enacted. Section 212 of PAMA, titled ''Delay in Transition from ICD–9 to ICD–10 Code Sets,'' provided that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d-2(c)) and section 162.1002 of title 45, Code of Federal Regulations.'' On May 1, 2014, the Secretary announced that HHS expected to issue an interim final rule that would require use of ICD–10–CM beginning October 1, 2015 and would continue to require use of ICD–9–CM through September 30, 2015. This announcement is available on the CMS Web site at *http://cms.gov/Medicare/Coding/ICD10/index.html*. HHS finalized the new compliance date of October 1, 2015 for ICD–10–CM and ICD–10–PCS in an August 4, 2014 final rule titled ''Administrative Simplification: Change to the Compliance Date for the International Classification of Diseases, 10th Revision (ICD–10–CM and ICD–10–PCS)'' (79 FR 45128). This rule also requires HIPAA covered entities to continue to use the ICD–9–CM code set through September 30, 2015. Therefore, beginning October 1, 2015, we require use of the ICD–10–CM and ICD–10–PCS codes for reporting the MS–DRG and comorbidity adjustment factors for IPF services.

Every year, changes to the ICD–10–CM and the ICD–10–PCS coding system will be addressed in the IPPS proposed and final rules. The changes to the codes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. The IPF PPS has always incorporated ICD–9–CM coding changes made in the annual IPPS update and will continue to do so for the ICD–10–CM and ICD–10–PCS coding changes. We will continue to publish coding changes in a Transmittal/Change Request, similar to how coding changes are announced by the IPPS and LTCH PPS. The coding changes relevant to the IPF PPS are also published in the IPF PPS proposed and final rules, or in IPF PPS update notices. In § 412.428(e), we indicate that CMS will publish information pertaining to the annual update for the IPF PPS, which includes describing the ICD–9–CM coding changes and DRG classification changes discussed in the annual update to the hospital IPPS regulations. Because ICD–10–CM will be implemented on October 1, 2015, we need to update the regulation language at § 412.428(e) to refer to ICD–10–CM, rather than ICD–9–CM. Therefore, we propose to revise § 412.428(e) to state that the information we will publish annually in the **Federal Register** to describe IPF PPS updates would describe the ICD–10–CM coding changes and DRG classification changes discussed in the annual update to the hospital inpatient prospective payment system regulations. In the FY 2015 IPF PPS final rule (79 FR 45945 through 46946), the MS–DRGs were converted so that the MS–DRG assignment logic uses ICD–10–CM/PCS codes directly. When an IPF submits a claim for discharges, the ICD–10–CM/PCS diagnosis and procedure codes will be assigned to the correct MS–DRG. In the FY 2015 IPF PPS final rule, we also identified the ICD–10–CM/PCS codes that are eligible for comorbidity payment adjustments under the IPF PPS (79 FR 45947 through 45955).

The ICD–10–CM guidelines are updated each year along with the ICD–10–CM code set. To find the annual coding guidelines, go to CDC's Web site at *http://www.cdc.gov/nchs/icd/icd10cm.htm* or the annual ICD–10–CM updates posted on the CMS ICD–10 Web site at *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

*B. Status of Future Refinements*

For RY 2012, we identified several areas of concern for future refinement, and we invited comments on these issues in our RY 2012 proposed and final rules. For further discussion of these issues and to review the public comments, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and final rule (76 FR 26432).

We have delayed making refinements to the IPF PPS until we have completed a thorough analysis of IPF PPS data on which to base those refinements. Specifically, we will delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We have begun the necessary analysis to better understand IPF industry practices so that we may refine the IPF PPS in the future, as appropriate.

IPF Covered Services

The IPF PPS established the Federal per diem base rate for each patient day in an IPF from the national average routine operating, ancillary, and capital costs. Preliminary analysis reveals that in 2012 to 2013, over 20 percent of IPF stays show no reported ancillary costs, such as laboratory and drug costs, in cost reports or charges on claims. The majority of these stays with zero ancillary costs or charges were in for-profit, free-standing IPF hospitals. We would expect that patients admitted to an IPF would undergo laboratory testing as part of the admission history and physical. We would also expect that most patients requiring hospitalization for active psychiatric treatment would need drugs. Therefore, we were surprised when the analysis showed such a large number of stays reporting no laboratory services and no drugs were provided throughout the hospitalization. Until further analysis is completed, we can only surmise that the stays did not require ancillaries and therefore, were not provided, or that the ancillary services were separately billed.

We remind the industry that CMS pays only the inpatient psychiatric facility for services furnished to a Medicare beneficiary who is an inpatient of that inpatient psychiatric facility, except for certain professional services, and that payments made under this subpart are payments in full for all inpatient hospital services, provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

The covered services specified in § 409.10(a), which apply to IPFs, include the following: Bed and board; nursing services and other related services; use of hospital or CAH facilities; medical social services; drugs, biologicals, supplies, appliances, and equipment; certain other diagnostic or therapeutic services; medical or surgical services provided by certain interns or residents-in-training; and transportation services, including transport by ambulance.

Only the professional services listed in § 409.10(b) can be separately billed for a Medicare beneficiary who is an inpatient at an IPF, including services of physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse mid-wives, anesthetists, and qualified psychologists. (see § 409.10(b) for specifics on how these professions and services are defined. These regulations are available online at the electronic Code of Federal Regulations, at *http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=%2Findex.tpl*.)

Ancillary costs such as laboratory costs and drugs are already included in the Medicare IPF PPS per diem payment and should not be unbundled and billed separately to Medicare. We expect that the IPF would be recording the cost of all drugs provided to its Medicare patients on its Medicare cost reports, and reporting charges for those drugs on its Medicare claims. We expect that when an IPF contracts with an outside laboratory to provide services to its

Medicare inpatients, the IPF would instruct the laboratory to bill the IPF and not to bill Medicare. Similarly, drugs provided to IPF Medicare inpatients where Medicare is the primary payer should not be billed to Part D or to other insurers.

We are continuing to analyze claims and cost report data that do not include ancillary charges or costs, and will be sharing our findings with the Center for Program Integrity and the Office of Financial Management for further investigation, as the results warrant. Our refinement analysis is dependent on recent precise data for costs, including ancillary costs. We will continue to collect these data until an accurate refinement analysis can be performed. Therefore, we are not proposing refinements in this proposed rule. Once we have gathered timely and accurate data, we will analyze that data with the expectation of a refinement update in future rulemaking. We invite comments on this issue of zero ancillary costs to better understand industry practices.

## V. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

### *A. Background*

#### 1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014 [2] and each subsequent fiscal year, the Secretary must reduce any annual update to a standard Federal rate for discharges occurring during the rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable fiscal year.

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than the payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary may not take into account the reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013, through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract.

Section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary must publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. These procedures must ensure that a facility has the opportunity to review its data prior to the data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on the CMS Web site.

#### 2. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (42 CFR 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with prior rules, we continue to use the term ''inpatient psychiatric facility'' (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at § 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

#### 3. Considerations in Selecting Quality Measures

Our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We refer readers to the FY 2013 IPPS/LTCH PPS final rule Section 4.a. (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration, which is published annually by December 1 on behalf of CMS by the NQF. In compliance with section 1890A(a)(2) of the Act, measures proposed for the IPFQR Program were included in 2 publicly available documents: ''List of Measures under Consideration for December 1, 2013,'' and ''List of Measures under Consideration for December 1, 2014'' (*http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*). The Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2014 and 2015 recommendations for quality measures under consideration are captured in the following

[2] The statute uses the term ''rate year'' (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD–9–CM codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the RY update period would be the 12-month period from October 1 through September 30, which we refer to as a ''fiscal year'' (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms ''rate year'', as used in the statute, and ''fiscal year'' as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

documents: ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs'' (*http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*) and ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' (*http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx*). We considered the input and recommendations provided by the MAP in selecting all measures for the Program, including those discussed below.

*B. Retention of IPFQR Program Measures Adopted in Previous Payment Determinations*

Since the inception of the IPFQR Program in FY 2013, we have adopted a total of 14 mandatory measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted six chart-abstracted IPF quality measures for the FY 2014 payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50895), we added 2 measures for the FY 2016 payment determination and subsequent years. In the FY 2015 IPF PPS final rule (79 FR 45963 through 45974), we finalized the addition of 2 new measures to the IPFQR Program to those already adopted for the FY 2016 payment determination and subsequent years, and finalized four quality measures for the FY 2017 payment determination and subsequent years.

*C. Proposed Removal of HBIPS–4 From the IPFQR Program Measure Set for the FY 2017 Payment Determination and Subsequent Years*

We first adopted HBIPS–4 Patients Discharged on Multiple Antipsychotic Medications in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53649 through 53650). We refer readers to that rule for a detailed discussion of the measure. At the time that we adopted the measure, it was NQF-endorsed and intended for use in conjunction with HBIPS–5 Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification. However, NQF removed its endorsement of HBIPS–4 in January 2014. The NQF's Behavioral Health Steering Committee, in its May 2014 Technical Expert Panel Report, found that current evidence indicated that HBIPS–4 ''does not allow for the distinction of differences in providers . . . .'' [3] Moreover, the Steering Committee noted that HBIPS–4 ''is not a measure of quality of patient care . . . and there is insufficient evidence to warrant the endorsement of this measure given the use of HBIPS–5, which addresses patients discharged on multiple antipsychotic medications with appropriate justification.'' [4] For these reasons, the Steering Committee did not re-endorse HBIPS–4.

As we stated in the FY 2013 IPPS/LTCH PPS final rule, we originally proposed HBIPS–4, in part, because HBIPS–4 and HBIPS–5 were intended to be reported as a set (77 FR 53649). However, as discussed above, NQF no longer believes HBIPS–4 is necessary in that set, and we agree. We have the authority to maintain measures that are not NQF-endorsed under section 1886(s)(4)(D)(ii) of the Act. However, based on the loss of NQF endorsement and because providers must still submit data for HBIPS–5, which we believe sufficiently includes the information HBIPS–4 was intended to collect, we believe removal of HBIPS–4 from the IPFQR Program is warranted. We note that the data collection period for FY 2016 has ended and providers are required to submit this data before this rule will be finalized. Therefore, FY 2017 is the first year that we would be able to remove this measure from the program.

In summary, Table 19, below, identifies the measure that we are proposing to remove beginning with the FY 2017 payment determination. We request comment on this proposal.

TABLE 19—IPFQR PROGRAM MEASURE PROPOSED TO BE REMOVED FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

| NQF No. | Measure ID | Measure |
|---|---|---|
| N/A | HBIPS–4 | Patients Discharged on Multiple Antipsychotic Medications |

*D. New Quality Measures Proposed for the FY 2018 Payment Determination and Subsequent Years*

For the FY 2018 payment determination and subsequent years, we are proposing five new measures. The sections below outline our rationale for proposing these measures.

1. TOB–3 Tobacco Use Treatment Provided or Offered at Discharge and the Subset Measure TOB–3a Tobacco Use Treatment at Discharge (NQF #1656)

Tobacco use is one of the greatest contributors of morbidity and mortality in the United States, accounting for more than 435,000 deaths annually.[5] Smoking is a known cause of multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease, other respiratory problems, poorer wound healing, and many other diseases.[6] This health issue has significant implications for persons with mental illness and substance use disorders. Tobacco use is much higher among people with co-existing mental health conditions than for the general population.[7] One study has estimated that these individuals are twice as likely to smoke as the rest of the population.[8] Tobacco use also creates a heavy financial cost to both individuals and society. Smoking-

[3] Behavioral Health Endorsement Maintenance 2014, Phase 2, Technical Report, 67, (May 9, 2014). Available at *http://www.qualityforum.org/Publications/2014/05/Behavioral_Health_Endorsement_Maintenance_2014_-_Phase_II.aspx*.

[4] *Ibid.*

[5] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004.'' *Morb Mortal Wkly Rep.* 2008. 57(45): 1226–1228. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm*.

[6] U.S. Department of Health and Human Services. ''The health consequences of smoking: a report of the Surgeon General.'' Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

[7] Fiore, Michael C., Goplerud, Eric, Shroeder, Steven A. (2010). The Joint Commission's New Tobacco Cessation Measures—Will Hospitals Do the Right Thing? *N Engl J Med* 2012; 366:1172–1174. Available at *http://www.nejm.org/doi/full/10.1056/nejmp1115176*.

[8] Lasser K, Boyd JW, Woolhandler S, Himmelstein, DU, McCormick D, Bor DH. Smoking and mental illness: A population-based prevalence study. *JAMA*. 2000;284(20):2606–2610.

attributable health care expenditures are estimated at $96 billion per year in direct medical expenses and $97 billion in lost productivity.[9]

Strong and consistent evidence demonstrates that timely tobacco dependence interventions for patients using tobacco can significantly reduce the risk of developing a tobacco-related disease, as well as provide improved health outcomes for those already suffering from a tobacco-related disease.[10] Even a minimal intervention has been shown to result in cessation.[11] Research discloses that tobacco users hospitalized with psychiatric illnesses who enter into smoking-cessation treatment can successfully overcome their tobacco dependence;[12] however, ''studies show that many hospitals do not consistently provide cessation services to their patients.''[13] Evidence also suggests that tobacco cessation treatment does not increase, and may even decrease, the risk of re-hospitalization for tobacco users hospitalized with psychiatric illnesses.[14] Research further demonstrates that effective tobacco cessation support across the care continuum can be provided with only minimal additional provider effort and without harm to the mental health recovery process.[15]

TOB–3 (NQF #1656) is a chart-abstracted measure that identifies those patients 18 years of age and older who have used tobacco products within 30 days of admission and who ''were referred to or refused evidence-based outpatient counseling *AND* received or refused a prescription for FDA-approved cessation medication upon discharge.''[16] TOB–3a is a subset of TOB–3 and identifies those IPF ''patients who were referred to evidence-based outpatient counseling *AND* received a prescription for FDA-approved cessation medication upon discharge as well as those who were referred to outpatient counseling and had reason for not receiving a prescription for medication.''[17] Providers must report this measure set as ''an overall rate which includes all patients to whom tobacco treatment was provided, or offered and refused, at the time of hospital discharge (TOB–3), and a second rate, a subset of the first, which includes only those patients who received tobacco use treatment at discharge. (TOB–3a).''[18] For more information on the measure specifications, we refer readers to the *Specifications Manual for National Hospital Inpatient Quality Measures* at *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482*. Providing counseling and recommending cessation medication are core strategies of the Treating Tobacco Use and Dependence Guidelines.[19] For the reasons stated above, we believe that adoption of the TOB–3/TOB–3a measure set, which assesses IPFs' offering of these tobacco use cessation treatments to IPF patients, would result in better overall health outcomes for IPF patients.

Furthermore, the adoption of this measure set would strengthen related measures already in place in the IPFQR Program. Currently, the IPFQR Program includes 2 other tobacco cessation measures: (1) Tobacco Use Screening (TOB–1), a chart-abstracted measure that assesses hospitalized patients who are screened within the first 3 days of admission for tobacco use (cigarettes, smokeless tobacco, pipe, and cigar) within the previous 30 days; and (2) The Tobacco Use Treatment Provided or Offered (TOB–2), which includes the subset, Tobacco Use Treatment (TOB–2a). TOB–2/TOB–2a is a chart-abstracted measure set reported as an overall rate that includes all patients to whom tobacco use treatment was provided, or offered and refused, and a second rate, a subset of the first, which includes only those patients who received tobacco use treatment. TOB–1 and TOB–2/TOB–2a provide a picture of care given *during the hospital stay.* In contrast, TOB–3/TOB–3a present the care given *at discharge.* Together, these 3 measures/measure sets present a broader picture of the entire episode of care. If the TOB–3/TOB–3a measure set is adopted, the IPFQR Program's measure set would showcase both the facility's practice of screening patients for tobacco use and the outcomes of a facility's practice of offering opportunities to stop during the course of the stay and upon discharge. Further, the adoption of TOB–3/TOB–3a could alert IPFs to gaps in treatment for smoking cessation intervention at discharge if rates for these measures are low. This knowledge would support the development of quality improvement plans and better engage patients in treatment.

We believe that public reporting of this information would provide consumers and other stakeholders with useful information in choosing among different facilities for patients who use tobacco products. In addition, this measure set promotes the National Quality Strategy priority of Effective Prevention and Treatment, particularly with respect to the leading causes of mortality, starting with cardiovascular disease. As noted above, tobacco use is one of the greatest contributors of morbidity and mortality in the United States,[20] contributing to various forms of cardiovascular disease, among many other conditions.[21] ''Tobacco use remains the chief preventable cause of illness and death in our society.''[22] Cessation interventions can significantly

[9] Centers for Disease Control and Prevention. ''Best Practices for Comprehensive Tobacco Control Programs—2007.'' Atlanta, GA, Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2007.

[10] U.S. Department of Health and Human Services. ''The health consequences of smoking: a report of the Surgeon General.'' Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

[11] Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update.* Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008, *available at http://www.ncbi.nlm.nih.gov/books/NBK63952.*

[12] Prochaska, JJ, et al. ''Efficacy of Initiating Tobacco Dependence Treatment in Inpatient Psychiatry: A Randomized Controlled Trial.'' *Am. J. Pub. Health.* 2013 August 15; e1-e9.

[13] Fiore, Michael C., Goplerud, Eric, Shroeder, Steven A. (2010). The Joint Commission's New Tobacco Cessation Measures—Will Hospitals Do the Right Thing? *N Engl J Med* 2012; 366:1172–1174, *available at http://www.nejm.org/doi/full/10.1056/nejmp1115176.*

[14] Prochaska, JJ, et al. ''Efficacy of Initiating Tobacco Dependence Treatment in Inpatient Psychiatry: A Randomized Controlled Trial.'' *Am. J. Pub. Health.* 2013 August 15; e1–e9.

[15] *Ibid.*

[16] TOB–3 and TOB–3a Measure Specifications, available at *http://www.jointcommission.org/assets/1/6/HIQR_Jan2015_v4_4a_1_EXE.zip*

[17] *Ibid.*

[18] TOB–3 and TOB–3a Measure Specifications, available at *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482.*

[19] *See* Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update.* Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008. Available at *http://www.ncbi.nlm.nih.gov/books/NBK63952.* The specific strategy is further specified in Strategy 4A.

[20] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004.'' *Morb Mortal Wkly Rep.* 2008. 57(45): 1226–1228. Available at: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm.*

[21] U.S. Department of Health and Human Services. ''The health consequences of smoking: a report of the Surgeon General.'' Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

[22] Fiore, Michael C., Goplerud, Eric, Shroeder, Steven A. (2010). The Joint Commission's New Tobacco Cessation Measures—Will Hospitals Do the Right Thing? *N Engl J Med* 2012; 366:1172–1174 Available at: *http://www.nejm.org/doi/full/10.1056/nejmp1115176.*

reduce the risk of developing tobacco-related disease,[23] leading to decreases in cardiovascular disease, among other diseases, and, ultimately, mortality. Encouraging intervention would promote effective treatment of tobacco use, and may contribute to prevention of the many diseases that are associated with tobacco use.

For these reasons, we included TOB–3/TOB–3a in our ''List of Measures under Consideration for December 1, 2014.'' The MAP provided input on the measure set and supported its inclusion in the IPFQR Program in its report ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*. Moreover, this measure set is NQF-endorsed for the IPF setting in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

We invite public comments on our proposal to adopt the TOB–3 and TOB–3a measure set for the FY 2018 payment determination and subsequent years.

2. SUB–2 Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention (NQF #1663)

Individuals with mental health conditions experience substance use disorders (SUDs) at a much higher rate than the general population. Individuals with the most serious mental illnesses have the highest rates of SUDs. Co-occurring SUDs often go undiagnosed and, without treatment, contribute to a longer persistence of disorders, poorer treatment outcomes, lower rates of medication adherence, and greater impairments to functioning.

Substance abuse, particularly alcohol abuse, is a significant problem in the elderly. Alcohol use disorders are the most prevalent type of addictive disorder in individuals ages 65 and over.[24] Roughly 6 percent of the elderly are considered to be heavy users of alcohol.[25] Alcohol abuse is often associated with depression and contributes to the etiology of many serious medical conditions, including liver disease and cardiovascular disease. For these reasons, it is important to assess IPFs' efforts to offer alcohol abuse treatment to those patients who screen positive for alcohol abuse.

SUB–2 includes ''[p]atients 18 years of age and older who screened positive for unhealthy alcohol use who received or refused a brief intervention during the hospital[26] stay.''[27] SUB–2a includes ''[p]atients who received the brief intervention during the hospital stay.''[28] The measure set is chart-abstracted and ''is reported as an overall rate which includes all patients to whom a brief intervention was provided, or offered and refused, and a second rate, a subset of the first, which includes only those patients who received a brief intervention.''[29] For more information on the measure specifications, we refer readers to the *Specifications Manual for National Hospital Inpatient Quality Measures* at *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482*.

We believe that the addition of the SUB–2/SUB–2a measure set to the related existing substance abuse measure in the IPFQR Program would improve the overall quality of care that patients receive in IPF settings, as well as overall patient health outcomes. We previously adopted the SUB–1 measure (Alcohol Use Screening (SUB–1) (NQF #1661)) (78 FR 50890 through 50892). SUB–1 assesses ''hospitalized patients 18 years of age and older who are screened during the hospital stay using a validated screening questionnaire for unhealthy alcohol use.'' SUB–1 alone does not provide a full picture of an IPF's response to this screening. However, when linked to SUB–2/SUB–2a, the IPF measure set depicts the rate at which patients are screened for potential alcohol abuse *and* the rate at which those who screen positive accept the offered interventions. Further, the adoption of SUB–2/SUB 2a could alert IPFs to gaps in treatment for interventions if rates are low, which supports the development of quality improvement plans and better patient engagement in treatment. In addition, data for the SUB–2/SUB–2a measure set, in combination with the SUB–1 measure, would afford consumers useful information in choosing among different facilities, particularly for patients who may require assistance with unhealthy alcohol use.

Additionally, we believe that this measure set promotes the National Quality Strategy priority of Effective Prevention and Treatment for the leading causes of mortality, starting with cardiovascular disease. As noted above, alcohol use disorders are the most prevalent type of addictive disorder in individuals ages 65 and over[30] and contribute to serious medical conditions, including cardiovascular disease and liver disease. Encouraging interventions would promote treatment of unhealthy alcohol use and may contribute to prevention of the many diseases that are associated with alcohol abuse, including cardiovascular disease.

For these reasons, we included the SUB–2/SUB–2a measure set in our ''List of Measures under Consideration for December 1, 2014.'' The MAP provided input on the measure set and supported its inclusion in the IPFQR Program in its report ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*. Moreover, this measure set is NQF-endorsed for the IPF setting, in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

We invite public comments on our proposal to adopt the SUB–2/SUB–2a measure set for the FY 2018 payment determination and subsequent years.

3. Transition Record With Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647) and Removal of HBIPS–6

Effective and timely communication of a patient's clinical status and other relevant information at the time of discharge from an inpatient facility is essential for supporting appropriate continuity of care. Establishment of an effective transition from one treatment setting to another is enhanced by providing patients and their caregivers with sufficient information regarding treatment during hospitalization. Receiving discharge instructions can assist the patient in understanding how

[23] U.S. Department of Health and Human Services. ''The health consequences of smoking: a report of the Surgeon General.'' Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

[24] *Ross, S. (2005). Alcohol Use Disorders in the Elderly. Primary Psychiatry, 12(1):32–40.*

[25] AL Mirand and JW Welte. Alcohol consumption among the elderly in a general population, Erie County, New York. *Am J Public Health*. 1996 July; 86(7): 978–984.

[26] Although the measure refers to ''hospitals,'' the measure is specified for all in-patient settings. *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482*.

[27] SUB–2 and SUB–2a Measure Specifications, available at *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482*.

[28] *Ibid*.

[29] SUB–2 and SUB–2a Measure Specifications, available at *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482*.

[30] Stephen Ross. Alcohol Use Disorders in the Elderly. Psychiatry Weekly (no date). Available at: *http://www.psychweekly.com/aspx/article/ArticleDetail.aspx?articleid=19*.

to maintain and enhance his/her care when discharged to home or any other site, and studies have shown that readmissions can be prevented by providing detailed, personalized information to patients pre-discharge.[31]

The Transition Record with Specified Elements Received by Discharged Patients (Discharges from on Inpatient Facility to Home/Self Care or Any other Site of Care) measure is a chart-abstracted measure that captures the ''[p]ercentage of patients, regardless of age, discharged from an inpatient facility to home or other site of care, or their caregiver(s), who received a transition record (and with whom a review of all included information was documented) at the time of discharge.'' [32] At a minimum, the transition record should include:

- Reason for inpatient admission;
- Major procedures and tests performed during inpatient stay and summary of results;
- Principal diagnosis at discharge;
- Current medication list;
- Studies pending at discharge;
- Patient instructions;
- Advance directive or surrogate decision maker documented or reason for not providing advance care plan;
- 24-hour/7-day contact information, including physician for emergencies related to inpatient stay;
- Contact information for obtaining results of studies pending at discharge;
- Plan for follow-up care; and
- Primary physician, other health care professional, or site designated for follow-up care.[33]

The measure was developed by the American Medical Association—convened Physician Consortium for Performance Improvement (AMA-convened PCPI), ''a national, physician-led initiative dedicated to improving patient health and safety.'' [34] For more information on this measure, including its specifications, we refer the readers to the AMA-convened PCPI list of measures at *http://www.qualityforum.org/Qps/0647*.

The Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any other Site of Care) measure seeks to prevent gaps in care transitions caused by the patient receiving inadequate or insufficient information that lead to avoidable adverse events and cost CMS approximately $15 billion due to avoidable patient readmissions.[35]

We believe that public reporting of this measure would afford patients and their families or caregivers useful information in choosing among different facilities and would promote the National Quality Strategy priority of Communication and Care Coordination. As articulated by HHS, ''Care coordination is a conscious effort to ensure that all key information needed to make clinical decisions is available to patients and providers. It is defined as the deliberate organization of patient care activities between 2 or more participants involved in a patient's care to facilitate appropriate delivery of health care services.'' [36] This proposed measure would promote appropriate care coordination by specifying that patients discharged from an inpatient facility receive relevant and meaningful transition information. This measure also would promote Person and Family Engagement, ''a set of behaviors by patients, family members, and health professionals and a set of organizational policies and procedures that foster both the inclusion of patients and family members as active members of the health care team and collaborative partnerships with providers and provider organizations.'' [37] This proposed measure would inform patients of their status at discharge, empowering them to become active members in their care. Additionally, the inclusion in this measure of an advance care plan would support open communication of the patient's, and his/her caregiver's/surrogate's, wishes, resulting in improved patient-provider communication.

For these reasons, we included this measure in our ''List of Measures under Consideration for December 1, 2014.'' The MAP provided input on the measure and supported its inclusion in the IPFQR Program in its report ''Process and Approach for MAP Pre-Rulemaking Deliberations 2015'' available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*. In addition, the MAP had previously suggested this measure as one that could fill a gap in communication between the provider and patient at discharge [38] and recommended that the measure be used for dual eligible patients (that is, patients with both Medicare and Medicaid coverage), who comprise a significant beneficiary population served within IPFs.[39] Moreover, this measure set is NQF-endorsed for the IPF setting, in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

If finalized, we propose that this measure would replace the existing HBIPS–6 Post-Discharge Continuing Care Plan measure.[40] We believe that the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure is a more effective and robust measure than HBIPS–6 for use in the IPF setting. Specifically, HBIPS–6 requires discharge plans to only have 4 components:

- Reason for hospitalization;
- Principal diagnosis;
- Discharge medications; and
- Next level of care recommendations.[41]

In contrast, the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure requires additional elements, including those described below, which are intended to improve quality of care, decrease costs, and increase beneficiary engagement.

First, the proposed measure requires the provider to communicate both studies pending at discharge as well as contact information so that patients or their families can obtain the results of those studies. Approximately 40 percent of discharged patients have test results

[31] Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization. *Ann Intern Med* 2009; 150:178–187.

[32] Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) Measure Specifications. Available at *http://www.qualityforum.org/Qps/0647*.

[33] *Ibid.*

[34] *See http://www.ama-assn.org/ama/pub/physician-resources/physician-consortium-performance-improvement/about-pcpi.page*? The AMA–PCPI ''is nationally recognized for measure development, specification and testing of measures, and enabling use of measures in electronic health records (EHRs) . . . [the organization] develops, tests, implements and disseminates evidence-based measures that reflect the best practices and best interest of medicine . . .''

[35] Medicare Payment Advisory Commission. Promoting Greater Efficiency in Medicare. June 2007. Available at: *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[36] US DHHS. ''National Healthcare Disparities Report 2013.'' Available at: *http://www.ahrq.gov/research/findings/nhqrdr/nhdr13/chap7.html*.

[37] Guide to Patient and Family Engagement: Environmental Scan Report. May 2012. Agency for Healthcare Research and Quality. Rockville, MD. Available at: *http://www.ahrq.gov/research/findings/final-reports/ptfamilyscan/ptfamily1.html*.

[38] *http://www.qualityforum.org/Publications/2012/10/MAP_Families_of_Measures.aspx*.

[39] *http://www.qualityforum.org/Publications/2014/08/2014_Input_on_Quality_Measures_for_Dual_Eligible_Beneficiaries.aspx*.

[40] In the FY 2013 IPPS/LTCH PPS final rule, we adopted HBIPS–6, beginning with the FY 2014 payment determination (77 FR 53650–53651). We refer readers to that rule for a detailed discussion of this measure.

[41] *See https://manual.jointcommission.org/releases/TJC2014A1/*.

that are pending and about a quarter of such test results require further action that, if not taken in a timely manner, could result in potentially avoidable negative outcomes.[42] HBIPS–6 does not require providers to specify studies pending at discharge.

Second, the transition record is also required to contain a list of major procedures and tests that were performed during the hospitalization and summary results. HBIPS–6 does not include this requirement. We believe it is important for a patient to understand which tests were performed on him/her and for what purpose, understanding the outcome and consequences of these tests. This knowledge may serve to empower patients to seek additional care or follow-up when necessary, reducing the risk of avoidable consequences and readmissions.

Third, the transition record in the proposed measure is required to include patient instructions while HBIPS–6 has no such requirement. Without instructions, the patient may not take the necessary steps for recovery, leading to complications and/or readmissions.

Fourth, the proposed measure requires both of the following: (1) 24-hour/7-day contact information including physicians for emergencies related to inpatient stay; and (2) the primary physician, other health care professional, or sites designated for follow-up care. HBIPS–6 does not have these requirements. Again, this information can lead to reduced complications and an increased likelihood of appropriate follow-up care, resulting in reduced readmissions.

Finally, the elements required for the proposed transition record measure are far better aligned than HBIPS–6 with the elements required in the Summary of Care record required by the Electronic Health Record (EHR) Incentive Program for eligible hospitals and critical access hospitals and with the guidance on discharge planning provided by the Medicare Learning Network available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Discharge-Planning-Booklet-ICN908184.pdf*.

In summary, we believe that the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure is more robust than HBIPS–6 because it includes these and other elements that are currently absent from HBIPS–6. Therefore, we propose to adopt the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure for the FY 2018 payment determination and subsequent years, and, if adopted, to remove HBIPS–6. We invite public comments on these proposals.

4. Timely Transmission of Transition Record (Discharges From an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) and Removal of HBIPS–7

The literature shows infrequent communication between hospital physicians and primary care practitioners and that the availability of discharge summaries at the patient's first post-discharge visit with the primary care practitioner is low, which affects the quality of care provided to patients.[43] The Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure (NQF #0648) is a chart-abstracted measure developed by AMA-convened PCPI to narrow gaps in care transition that result in adverse health outcomes for patients and cost CMS about $15 billion due to readmissions,[44] as discussed above. This measure captures the ''[p]ercentage of patients, regardless of age, discharged from an inpatient facility to home or any other site of care for whom a transition record was transmitted to the facility or primary physician or other health care professional designated for follow-up care within 24 hours of discharge.''[45] For more information on this measure, including its specifications, we refer the readers to *http://www.qualityforum.org/Qps/0648*.

We believe that public reporting of this measure will afford consumers, and their families or caregivers, useful information in choosing among different facilities because it communicates how quickly a summary of the patient's record will be transmitted to his or her other treating facilities and physicians, improving care, as outlined above. We further believe that this measure will promote the National Quality Strategy priority of Communication and Care Coordination. As discussed above, according to HHS, ''Care coordination is a conscious effort to ensure that all key information needed to make clinical decisions is available to patients and providers. It is defined as the deliberate organization of patient care activities between 2 or more participants involved in a patient's care to facilitate appropriate delivery of health care services.''[46] This proposed measure enables a patient's primary care physician or other healthcare practitioner to timely receive a transition record of the inpatient hospitalization.

For these reasons, we included this measure in our ''List of Measures under Consideration for December 1, 2014.'' The MAP provided input on the measure and supported its inclusion in the IPFQR Program (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*). In addition, the MAP had previously suggested this measure as one that could fill a gap in communication[47] and recommended that the measure be used for dual eligible patients (that is, patients with both Medicare and Medicaid coverage), who comprise a significant beneficiary population served within IPFs.[48] Moreover, this measure set is NQF-endorsed for the IPF setting, in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

If finalized, we propose that this measure would replace the existing HBIPS–7 Post Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge measure.[49] HBIPS–7 requires that the continuing care plan be transmitted to the next care provider no later than the fifth day post discharge.[50] The Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure requires transmission to the next level of care within 24 hours

[42] Kripalani S, LeFevre F, Phillips CO, et al. Deficits in communication and information transfer between hospital based and primary care physicians: implications for patient safety and continuity of care. *JAMA*2007;297(8):831–841.

[43] Kripalani S, LeFevre F, Phillips CO, et al. Deficits in communication and information transfer between hospital based and primary care physicians: implications for patient safety and continuity of care. JAMA 2007;297(8):831–841.

[44] Medicare Payment Advisory Commission. Promoting Greater Efficiency in Medicare. June 2007. Available at: *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[45] Timely Transmission of Transition Record (Discharged from Inpatient Facility to Home/Self Care or Any Other Site of Care), available at *http://www.ama-assn.sorg/apps/listserv/x-check/qmeasure.cgi?submit=PCPI*.

[46] US DHHS. ''National Healthcare Disparities Report 2013.'' Available at: *http://www.ahrq.gov/research/findings/nhqrdr/nhdr13/chap7.html*.

[47] *http://www.qualityforum.org/Publications/2012/10/MAP_Families_of_Measures.aspx*.

[48] *http://www.qualityforum.org/Publications/2014/08/2014_Input_on_Quality_Measures_for_Dual_Eligible_Beneficiaries.aspx*.

[49] In the FY 2013 IPPS/LTCH PPS final rule, we adopted HBIPS–7 Post Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge, beginning with the FY 2014 payment determination (77 FR 53651–53652). We refer readers to that rule for a detailed discussion of this measure.

[50] *https://manual.jointcommission.org/releases/TJC2014A1/*.

of discharge. More timely communication of vital information regarding the inpatient hospitalization results in better care, reduction of systemic medical errors, and improved patient outcomes. Studies show that the risks of re-hospitalization are lower when primary care providers have access to patients' post-discharge records at the first post-discharge visit,[51] [52] which may be within a day (or days) of discharge. Critically, the availability of the discharge record to the next level provider within 24 hours after discharge supports more effective care coordination and patient safety, since a delay in communication can result in medication or treatment errors. Thus, we believe that replacing HBIPS–7 with the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure would increase the quality of care provided to patients, reduce avoidable readmissions, and increase patient safety.

We invite public comments on our proposals to adopt the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure for the FY 2018 payment determination and subsequent years and, if adopted, our removal of HBIPS–7.

5. Screening for Metabolic Disorders

Studies show that both second generation antipsychotics (SGAs) and antipsychotics increase the risk of metabolic syndrome.[53] Metabolic syndrome involves a cluster of conditions that occur together, including excess body fat around the waist, high blood sugar, high cholesterol, and high blood pressure, and increases the risk of coronary artery disease, stroke, and type 2 diabetes. Recognizing this problem, in February 2004, the American Diabetes Association (ADA), the American Psychiatric Association (APA), the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity released a consensus statement finding that the use of SGAs ''have been associated with reports of dramatic weight gain, diabetes (even acute metabolic decompensation, for example, diabetic ketoacidosis [DKA]), and an atherogenic lipid profile (increased LDL cholesterol and triglyceride levels and decreased HDL cholesterol) . . . [and] [s]ubsequent drug surveillance and retrospective database analyses suggest that there is an association between specific SGAs and both diabetes and obesity.'' [54] SGAs also have an effect on serum lipids and could result in dyslipidemia.[55] Given these concerns, the group recommended that ''baseline screening measures be obtained before, or as soon as clinically feasible after, the initiation of any antipsychotic medication,'' including body mass index (BMI), blood pressure, fasting plasma glucose, and fasting lipid profile.[56] Although the consensus statement specifically discussed the issues with SGAs, the ADA also emphasized that ''*all* patients receiving antipsychotic medications [should] be screened'' [57] and subsequent studies have found that ''[i]n schizophrenic patients, the level of lipid profile had been increased in *both* atypical and conventional antipsychotic users'' [58]

Numerous other organizations have also made similar recommendations.[59] For example, the National Association of State Mental Health Program Directors Medical Directors Council notes, ''the second generation antipsychotic medications have become more highly associated with weight gain, diabetes, dyslipidemia, insulin resistance, and the metabolic syndrome.'' They recommend the same screening as the consensus statement (BMI, blood pressure, fasting plasma glucose, and fasting lipid profile) and emphasize that this screening is ''the standard of care for the general population.'' [60] Likewise, the Mount Sinai Conference,[61] convened in 2002, recommended that, for every patient with schizophrenia, ''regardless of the antipsychotic prescribed,'' mental health providers should, among other things: (1) Monitor and chart BMI; (2) measure plasma glucose levels (fasting or HbA1c); and (3) obtain a lipid profile.[62]

Despite these consensus statements and guidelines, many of which are over a decade old, screening for metabolic syndrome remains low and there appears to be disagreement regarding where the responsibility for this screening lies.[63] Studies show a systematic lack of metabolic risk monitoring of patients who have been prescribed antipsychotics.[64] Screening for metabolic syndrome may reduce the risk of preventable adverse events and improve the physical health status of the patient. Therefore, we believe it is necessary to include a measure of metabolic syndrome screening in the IPFQR Program.

The Screening for Metabolic Disorders measure is a chart-abstracted measure

[51] van Walraven C, Seth R, Austin PC, Laupacis A. (2002). Effect of discharge summary availability during postdischarge visits on hospital readmission. *Journal of General Internal Medicine* 17:186–192.

[52] Jack BW, Chetty VK, Anthony D, et al. (2009). A reengineered hospital discharge program to decrease rehospitalization. *Ann Intern Med.150* (3),178–187.

[53] The American Diabetes Association, APA, the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity (2004). Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care, 27,* 596–601. Marder, Stephen R., M.D., et al. Physical Health Monitoring of Patients with Schizophrenia. Am J Psychiatry. 2004 Aug;161(8):1334–49.

[54] The American Diabetes Association, APA, the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity (2004). Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care, 27,* 596–601.

[55] *Ibid.*

[56] *Ibid.*

[57] The American Diabetes Association (2006). Antipsychotic Medications and the Risk of Diabetes and Cardiovascular Disease. Available at: *http://professional.diabetes.org/admin/UserFiles/file/CE/AntiPsych%20Meds/Professional%20Tool%20%231(1).pdf* (emphasis added).

[58] Roohafsza, H, Khani, A, Afshar, H, Garakyaraghi, A, Ghodsi, B. Lipid profile in antipsychotic drug users: A comparative study. *ARYA Atheroscler.* May 2013; 9(3): 198–202 (emphasis added).

[59] De Hert, M., Dekker, J.M. & Wood, D. (2009). Cardiovascular disease and diabetes in people with severe mental illness. Position statement from the European Psychiatric Association (EPA), supported by the European Association for the Study of Diabetes (EASD) and the European Society of Cardiology (ESC). *Eur Psychiatry, 24,* 412–424; Zolnierek, C.D. (2009). Non-psychiatric hospitalization of people with mental illnesses: A systematic review. *Journal of Advanced Nursing, 65*(8), 1570–1583.

[60] National Association of State Mental Health Program Directors Medical Directors Council (2006). Morbidity and mortality in people with serious mental illness. Available at: *http://www.nasmhpd.org/docs/publications/MDCdocs/Mortality%20and%20Morbidity%20Final%20Report%208.18.08.pdf.*

[61] The Mount Sinai Conference was conferred to ''focus on specific questions regarding the pharmacotherapy of schizophrenia . . . Participants in the conference were selected based on their knowledge of and contributions to the literature in this area . . . Also in attendance [were] various groups concerned with improving psychopharmacology in routine practice settings.'' Marder, Stephen R., M.D., et al. Physical Health Monitoring of Patients with Schizophrenia. Am J Psychiatry. 2004 Aug;161(8):1334–49.

[62] Marder, Stephen R., M.D., et al. Physical Health Monitoring of Patients with Schizophrenia. Am J Psychiatry. 2004 Aug;161(8):1334–49.

[63] *See e.g.,* Brooks, Megan. ''Metabolic Screening in Antipsychotic Users: Whose Job Is It?'' *Medscape Medical News.* 8 May 2012. Available at *http://www.medscape.com/viewarticle/763468.* Mittal D, Li C, Viverito K, Williams JS, Landes RD, Thapa PB, Owen R. Monitoring for metabolic side effects among outpatients with dementia receiving antipsychotics. *Psychiatr Serv.* 2014 Sep 1;65(9):1147–53.

[64] Nasrallah, H. A, MD (2012). There is no excuse for failing to provide metabolic monitoring for patients receiving antipsychotics. Current Psychiatry, 4 (citing Mitchell AJ, Delaffon V, Vancampfort D, et al. Guideline concordant monitoring of metabolic risk in people treated with antipsychotic medication: systematic review and meta-analysis of screening practices. *Psychol Med.* 2012;42(1):125–147.)

developed by CMS and defined as a percentage of discharges from an IPF for which a structured metabolic screening for 4 elements was completed in the past year. The denominator includes IPF patients discharged with one or more routinely scheduled antipsychotic medications during the measurement period. The numerator is the total number of patients who received a metabolic screening either prior to, or during, the index IPF stay. The screening must contain four tests: (1) BMI; (2) blood pressure; (3) glucose or HbA1c; and (4) a lipid panel—which includes total cholesterol (TC), triglycerides (TG), high density lipoprotein (HDL), and low density lipoprotein (LDL–C) levels. The screening must have been completed at least once in the 12 months prior to the patient's date of discharge. Screenings can be conducted either at the reporting facility or another facility for which records are available to the reporting facility. The following patients are excluded from the measure: (1) Patients for whom a screening could not be completed within the stay due to the patient's enduring unstable medical or psychological condition; and (2) patients with a length of stay equal to or greater than 365 days, or less than 3 days. In section F.3. below, we propose a sampling methodology for this and certain other measures.

Testing of this measure demonstrated that performance on the metabolic screening measure was low, on average, across the tested IPFs. The measure's average performance rate of 42 percent signals a strong opportunity for improvement. During testing, the metabolic screening measure also demonstrated nontrivial variation in performance among IPFs (6.2–98.6 percent). In addition, it demonstrated near-perfect agreement between chart abstractors (kappa of 0.93 for the measure numerator).[65]

We included the Screening for Metabolic Disorders measure (then titled ''IPF Metabolic Screening'') in our ''Measures Under Consideration List'' in December 2013. The MAP did not recommend this measure, noting, ''a different NQF-endorsed measure better addresses the needs of the program.''[66] However, the different NQF-endorsed measure was not identified by the MAP, and we are unaware of any screening measures for metabolic syndrome that are NQF-endorsed. We note that, when presented to the MAP, the denominator for this measure was the ''total number of psychiatric inpatients admitted during the measurement period.'' Based on testing and further feedback on the measure, we revised the measure by reducing its application to only those patients on antipsychotic medication; the denominator for the measure is now ''IPF patients discharged with one or more routinely scheduled antipsychotic medications during the measurement period.'' We believe that this change was appropriate because, as discussed above, the patients most at risk for metabolic syndrome are those receiving antipsychotics and the APA and other consensus organizations recommend this screening for patients on antipsychotics. Furthermore, by limiting the application of the measure only to those receiving antipsychotics, we believe that we have reduced provider burden, both in terms of possible changes in practice that might result from the measure, as well as the direct burden resulting from its collection and reporting.

We believe that this measure promotes the National Quality Strategy priority of Making Care Safer, which seeks to reduce risk that is caused by the delivery of healthcare. As discussed above, antipsychotics have been shown to be related to metabolic syndrome. The Screening for Metabolic Disorders measure is aimed at the prevention and treatment of serious side effects of these drugs.

Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have been unable to identify any measures addressing screening for metabolic syndrome for the IPF setting that have been endorsed by the NQF or adopted by any other consensus organization. We believe the proposed measure for the Screening for Metabolic Disorders meets the measure selection exception requirement under section 1886(s)(4)(D)(ii) of the Act.

We invite public comments on our proposal to adopt this measure for the FY 2018 payment determination and subsequent years.

6. Summary of Measures Proposed for Adoption and Removal for FY 2018 and Subsequent Years

The measures that we are proposing to add to the IPFQR Program for the FY 2018 payment determination and subsequent years are set forth in Table 20, below.

TABLE 20—IPFQR PROGRAM MEASURES PROPOSED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

| National Quality Strategy priority | NQF No. | Measure ID | Measure |
|---|---|---|---|
| Effective Prevention and Treatment | 1656 | TOB–3 and TOB–3a. | Tobacco Use Treatment Provided or Offered at Discharge and the subset measure Tobacco Use Treatment at Discharge. |
| Effective Prevention and Treatment | 1663 | SUB–2 and SUB–2a. | Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention. |
| Communication and Care Coordination; Person and Family Engagement. | 0647 | N/A | Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care). |
| Communication and Care Coordination | 0648 | N/A | Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care). |

[65] Development of Quality Measures for Inpatient Psychiatric Facilities. February 2015. U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, Office of Disability, Aging, and Long-term Care Policy. Page xi, at *http://aspe.hhs.gov/daltcp/reports/2015/ipf.cfm*.

[66] MAP 2014 Recommendations on Measures for More than 20 Federal Programs, 179, at *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*.

TABLE 20—IPFQR PROGRAM MEASURES PROPOSED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

| National Quality Strategy priority | NQF No. | Measure ID | Measure |
|---|---|---|---|
| Making Care Safer | N/A | N/A | Screening for Metabolic Disorders. |

The measures that we are proposing to remove beginning with the FY 2018 payment determination are set forth in Table 21, below.

TABLE 21—IPFQR PROGRAM MEASURES PROPOSED TO BE REMOVED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

| NQF No. | Measure ID | Measure |
|---|---|---|
| 0557 | HBIPS–6 | Post-Discharge Continuing Care Plan (Removal of measure contingent upon adoption of proposed measure, Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)). |
| 0558 | HBIPS–7 | Post Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge (Removal of measure contingent upon adoption of proposed measure, Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)). |

If these proposals are adopted, the number of measures for the FY 2018 IPFQR Program would total 16, as set forth in Table 22, below.

TABLE 22—PREVIOUSLY ADOPTED AND PROPOSED MEASURES FOR FY 2018 AND SUBSEQUENT YEARS

| NQF No. | Measure ID | Measure |
|---|---|---|
| 0640 | HBIPS–2 | Hours of Physical Restraint Use. |
| 0641 | HBIPS–3 | Hours of Seclusion Use. |
| 0560 | HBIPS–5 | Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification. |
| 0576 | FUH | Follow-up After Hospitalization for Mental Illness. |
| 1661 | SUB–1 | Alcohol Use Screening. |
| 1663 | SUB–2 and SUB–2a | Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention.* |
| 1651 | TOB–1 | Tobacco Use Screening. |
| 1654 | TOB–2 | Tobacco Use Treatment Provided or Offered and |
| | TOB–2a | Tobacco Use Treatment. |
| 1656 | TOB–3 and TOB–3a | Tobacco Use Treatment Provided or Offered at Discharge and the subset measure Tobacco Use Treatment at Discharge.* |
| 1659 | IMM–2 | Influenza Immunization. |
| 0647 | N/A | Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).* |
| 0648 | N/A | Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).* |
| N/A | N/A | Screening for Metabolic Disorders.* |
| N/A | N/A | Influenza Vaccination Coverage Among Healthcare Personnel. |
| N/A | N/A | Assessment of Patient Experience of Care. |
| N/A | N/A | Use of an Electronic Health Record. |

* Measures proposed for the FY 2018 payment determination and future years.

*E. Possible IPFQR Program Measures and Topics for Future Consideration*

As we have previously indicated (79 FR 45974 through 45975), we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting. Therefore, through future rulemaking, we intend to propose new measures that will help further our goals of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services through the widespread dissemination and use of quality information.

We are developing a 30-day psychiatric readmission measure that is similar to the readmission measures currently in use for other CMS quality reporting programs, such as the Hospital Inpatient Quality Reporting Program. We anticipate that we will recommend additional measures for development or adoption in the future. We intend to develop a measure set that effectively assesses IPF quality across the range of services and diagnoses, encompasses all of the goals of the CMS quality strategy, addresses measure gaps identified by the MAP and others, and minimizes collection and reporting burden. We may also propose the removal of some measures in the future.

We invite public comment on measures that we should consider.

*F. Changes to Reporting Requirements*

We are proposing to make the following changes to our reporting requirements for FY 2017 and subsequent years:

• Requiring that measures be reported as a single yearly count rather than by quarter and age; and

• Requiring that aggregate population counts be reported as a single yearly number rather than by quarter.

For FY 2018 and subsequent years we are also proposing to make one change, allowing uniform sampling requirements for certain measures.

1. Proposed Changes to Reporting by Age and Quarter for FY 2017 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53656), we finalized our policy that IPFs must submit data for chart-abstracted measures to the Web-Based Measures Tool on an annual basis aggregated by quarter. We also finalized our policy that IPFs must submit data as required by The Joint Commission, which calls for IPFs to submit data for measures by age group. Since then, we have learned that obtaining data for each quarter and by age is burdensome to providers and the resultant number of cases is often too small to allow public reporting. That is, we do not report data on *Hospital Compare* for measures with fewer than 11 cases; reporting by age and quarter often causes the number of cases to fall below 11. For example, for HBIPS–5, in Quarter 2 of 2013, only 5.75 percent of the data were reportable. Likewise, in Quarter 3 and Quarter 4 of 2013, for HBIPS–5, only 5.5 percent of the data were reportable.

Therefore, beginning with FY 2017, we propose to require facilities to report data for chart-abstracted measures to the Web-Based Measures Tool on an aggregate basis by year, rather than by quarter, and to discontinue the requirement for reporting by age group. If adopted, we would require IPFs to report a single aggregate measure rate for each measure annually for each payment determination.

We believe that this change would reduce provider burden because IPFs would report a single rate for each measure. In addition, we do not believe that quarterly data or data stratified by age are necessary for quality improvement activities. We are able to differentiate, and the public is able to view on *Hospital Compare,* those IPFs that perform well on measures from those for which quality improvement activities may be necessary based on an annual aggregate rate submission. We note, however, that in the future, if our evolving measures set, quality improvement goals, and experience with the program indicate a change is needed, we may reevaluate and reinstate the requirement for quarterly reporting.

In Table 23, below, we set forth the proposed quality reporting and submission timelines for the FY 2017 payment determination and subsequent years for all the measures except FUH and the Influenza Vaccination Coverage among Healthcare Personnel measures. We note that FUH is claims-based, and therefore does not require additional data submission. The Influenza Vaccination Coverage among Healthcare Personnel measure is reported to the Centers for Disease Control and Prevention, and we refer readers to the FY 2015 IPF PPS final rule for more information on the reporting timeline for this measure (79 FR 45969).

TABLE 23—PROPOSED QUALITY REPORTING PERIODS AND TIMEFRAMES FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

| Payment determination (FY) | Reporting period for services provided | Data submission timeframe |
|---|---|---|
| 2017 | January 1, 2015–December 31, 2015 | July 1, 2016–August 15, 2016. |

We invite public comment on this proposal.

2. Proposed Changes To Aggregate Population Count Reporting for FY 2017 Payment Determination and Subsequent Years

In the FY 2015 IPF PPS final rule (79 FR 45973), we finalized our policy that IPFs must submit aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for measures for which sampling is performed. In section V.F.1. of this proposed rule, we are proposing to only require measure reporting as an annual aggregate rate, rather than by quarter. Likewise, beginning with the FY 2017 payment determination, we propose to require non-measure data to be reported as an aggregate, yearly count rather. We invite public comment on this proposal.

3. Proposed Changes to Sampling Requirements for FY 2018 Payment Determination and Subsequent Years

Measure specifications for the measures that we have adopted and propose to adopt allow sampling for some measures; however, for other measures, IPFs must report data for all discharges/patients. In addition, the sampling requirements sometimes vary by measure. In response to these policies, in the FY 2014 IPPS/LTCH PPS final rule, some commenters noted that different sampling requirements in the measures could increase burden on facilities because these differences would require IPFs to have varying policies and procedures in place for each measure (78 FR 50901). Although we stated our belief that the importance of these measures and of gathering information for all discharges/patients outweighs the burden of various sampling requirements, we now believe that the additional measures proposed in this proposed rule tip the balance of benefit and burden. Therefore, and for the reasons provided below, we are proposing to allow a uniform sampling methodology both for measures that require sampling and for certain other measures. Specifically, we propose to allow The Joint Commission/CMS Global Initial Patient Population sampling in Section 2.9_Global Initial Patient Population found at *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228773989482*. If this proposal is finalized, it will allow IPFs to take one, global sample for all measures specified in Table 24, thereby decreasing burden on these facilities and streamlining policies and procedures.

In our current and proposed measure set, the measures for which we propose to allow The Joint Commission/CMS Global sampling would include those outlined in Table 24, below.

TABLE 24—MEASURES TO WHICH PROPOSED SAMPLING APPLIES *

| NQF No. | Measure ID | Measure |
|---|---|---|
| 0560 | HBIPS–5 | Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification. |

TABLE 24—MEASURES TO WHICH PROPOSED SAMPLING APPLIES *—Continued

| NQF No. | Measure ID | Measure |
|---|---|---|
| 1661 | SUB–1 | Alcohol Use Screening. |
| 1663 | SUB–2 and SUB–2a | Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention.** |
| 1651 | TOB–1 | Tobacco Use Screening. |
| 1654 | TOB–2<br>TOB–2a | Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment. |
| 1656 | TOB–3 and TOB–3a | Tobacco Use Treatment Provided or Offered at Discharge and the subset measure Tobacco Use Treatment at Discharge.** |
| 1659 | IMM–2 | Influenza Immunization. |
| 0647 | N/A | Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).** |
| 0648 | N/A | Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).** |
| N/A | N/A | Screening for Metabolic Disorders.** |

* Measures proposed for removal have not been included in this table. If these measures (HBIPS–4, HBIPS–6, and HBIPS–7) are not removed, the sampling methodology would also apply to their collection and submission.
** Measures proposed for the FY 2018 payment determination and future years.

In section F.1. of this proposed rule, we are proposing to require reporting on measures as a yearly count rather than by quarter. Because The Joint Commission/CMS Global sampling guidelines specify sampling by quarter, we propose to modify their sampling guidelines by multiplying the ''number of cases in the initial patient population'' and the ''number of cases to be sampled'' by 4. In addition, since we require all IPFs to report data on all chart-abstracted measures even when the population size for a given measure is small or zero (78 FR 50901), we have modified the table to require reporting regardless of the number of cases. Thus, we propose the following sampling guidelines for the measures above:

| Number of cases in initial patient population | Number of records to be sampled |
|---|---|
| ≥ 6,117 | 1,224. |
| 3,057–6,116 | 20% of initial patient population. |
| 609–3,056 | 609. |
| 0–608 | All cases. |

As stated above, we believe this proposal will simplify processes and procedures for IPFs because uniform requirements will promote streamlined procedures and reporting. We also believe the proposal will decrease burden by allowing IPFs to identify a single, initial patient population for all of the measures specified in Table 24 from which to calculate the sample size. Furthermore, we do not believe this approach will reduce quality improvement. Sampling calculations ensure that enough data are represented in the sample to determine accurate measure rates. Therefore, even with sampling, we believe that CMS, IPFs, and the public would be able to differentiate those IPFs who perform well on measures from those who do not.

We invite public comment on this proposal, which would begin with the FY 2018 payment determination.

*G. Public Display and Review Requirements*

We are not proposing any changes to the public display and review requirements for the FY 2018 payment determination and subsequent years and refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898) for more information.

*H. Form, Manner, and Timing of Quality Data Submission*

1. Procedural and Submission Requirements

We are not proposing any changes to the procedural and submission requirements for the FY 2018 payment determination and subsequent years and refer readers to the FY 2014 IPPS/LTCH PPS final rule (77 FR 50898 through 50899) for more information on these previously finalized requirements.

2. Proposed Change to the Reporting Periods and Submission Timeframes

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901), we finalized requirements for reporting periods and submission timeframes for the IPFQR Program measures. We are proposing one change to these requirements, as discussed above in section V.F.1. of this proposed rule. Specifically, we are proposing to no longer require that measure rates be reported quarterly and by age, but to only require an aggregate, yearly count.

3. Population and Sampling

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 58901 through 58902), we finalized policies for population, sampling, and minimum case thresholds. We are proposing one change to these policies, as discussed above in section V.F.3. of this proposed rule. Specifically, we are proposing to allow uniform sampling on certain measures.

4. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We are not proposing any changes to the DACA requirements and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for more information on these requirements.

*I. Reconsideration and Appeals Procedures*

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660), we adopted a reconsideration process, later codified at § 412.434, whereby IPFs can request a reconsideration of their payment update reduction in the event that an IPF believes that its annual payment update has been incorrectly reduced for failure to meet all IPFQR Program requirements. We are not proposing any changes to the Reconsideration and Appeals Procedure and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50953) for further details on the reconsideration process.

*J. Exceptions to Quality Reporting Requirements*

We are not proposing any changes to the exceptions to quality reporting requirements and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), where we initially finalized the policy as ''Waivers

from Quality Reporting,'' and the FY 2015 IPF PPS final rule (79 FR 45978), where we re-named the policy as ''Exceptions to Quality Reporting Requirements'' for more information.

## VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 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, PRA section 3506(c)(2)(A) 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

*A. Wage Estimates*

We estimate that reporting data for the IPFQR Program measures can be accomplished by staff with a mean hourly wage of $16.42 per hour.[67] Under OMB Circular A–76, in calculating direct labor, agencies should not only include salaries and wages, but also ''other entitlements'' such as fringe benefits.[68] This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $22.37 ($16.42 base salary + $5.95 fringe). The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 36.25 percent of salary), and the adjusted hourly wage.

| Occupation title | Occupation code | Mean hourly wage ($/hr) | Fringe benefit (at 36.25% in $/hr) | Adjusted hourly wage ($/hr) |
|---|---|---|---|---|
| Medical Records and Health Information Technician | 29–2071 | 16.42 | 5.95 | $22.37 |

The BLS is ''the principal Federal agency responsible for measuring labor market activity, working conditions, and price changes in the economy.''[69] Acting as an independent agency, the Bureau provides objective information for not only the government, but also for the public. The Bureau's National Occupational Employment and Wage Estimates describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data. Therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for these measures. In addition, the Hospital IQR Program uses this wage to calculate its burden estimates.

*B. ICRs Regarding the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program*

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45978 through 45980) for a detailed discussion of the burden for the program requirements that we have previously adopted. Below, we discuss only the changes in burden resulting from the provisions in this proposed rule. Although we propose provisions that impact both the FY 2017 and FY 2018 payment determinations, all of our proposals begin to apply to facilities in FY 2016. For example, data collection for the proposed measures begins in FY 2016, and the changes to the reporting requirements take effect beginning with reporting that is required in the summer of FY 2016. For purposes of calculating burden, we will attribute the costs associated with the proposals to the year in which these costs begin; for the purposes of all of the provisions in this proposed rule, that year is FY 2016.

1. Changes in Time Required To Chart-Abstract Data Based on Proposed Reporting Requirements

As discussed in section V.F. of this preamble, we are proposing the following 3 changes regarding how facilities should report data for IPFQR Program measures: (1) Measures must be reported as a single yearly count rather than by quarter and age; (2) aggregate population counts must be reported as a single yearly number rather than by quarter; and (3) uniform sampling would be allowed for certain measures.

We believe that these changes will lead to a decrease in burden since facilities would only be required to enter one aggregate number for both the numerator and denominator for each measure and will be allowed to pull one sample used to calculate the measures specified in Table 24 of this preamble. Consequently, we believe that the time required to chart-abstract data for these measures would be reduced by 20 percent. Previously, we estimated 15 minutes to chart-abstract data for each case (79 FR 45979). Because of our proposed changes to sampling and reporting data, we are revising the figure and now estimate 12 minutes ($0.20 \times 15$ minutes), a change of $-3$ min or $-0.05$ hr.

2. Estimated Burden of IPFQR Program Proposals

In section V. of this preamble, we are proposing to adopt the following five measures:

- TOB–3—Tobacco Use Treatment Provided or Offered at Discharge and the subset measure TOB–3a Tobacco Use Treatment at Discharge (National Quality Forum (NQF) #1656);
- SUB–2—Alcohol Use Brief Intervention Provided or Offered and the subset measure SUB–2a (NQF #1663);
- Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647);
- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648); and
- Screening for Metabolic Disorders.

In the same section, we are also proposing to remove the following 3 measures:

- HBIPS–4 Patients Discharged on Multiple Antipsychotic Medications;
- Hospital Based Inpatient Psychiatric Services (HBIPS)-6 Post-Discharge Continuing Care Plan (NQF #0557), if Transition Record with Specified Elements Received by Discharged Patients (Discharges from an

[67] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

[68] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

[69] *http://www.bls.gov/bls/infohome.htm.*

Inpatient Facility to Home/Self Care or Any Other Site of Care) is adopted; and

- HBIPS–7 Post-Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge (NQF #0558), if Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648) is adopted.

We believe that approximately 1,617 [70] IPFs will participate in the IPFQR Program for requirements occurring in FY 2016 and subsequent years. Based on data from CY 2013, we believe that each facility will submit measure data on approximately 431 [71] cases per year. Therefore, we estimate that adopting five measures and removing 3 measures (for a net result of 2 measures) will result in an increase in burden of 172.4 hours per facility (2 measures × (431 cases/measure × 0.20 hours/case)) or 278,770.80 hours across all IPFs (172.4 hours/facility × 1,617 facilities). The increase in costs is approximately $3,856.59 per IPF ($22.37/hour × 172.4 hours) or $6,236,102.80 across all IPFs (278,770.80 hours × $22.37/hour).

Consistent with our estimates in the FY 2015 IPF PPS final rule (79 FR 45979), we believe the estimated burden for training personnel on our proposals for data collection and submission is 2 hours per facility or 3,234 hours (2 hours/facility × 1,617 facilities) across all IPFs. Therefore, the cost for this training is $44.74 ($22.37/hour × 2 hours) for each IPF or $72,344.58 ($22.37/hour × 3,234 hours) for all facilities.

Finally, IPFs must submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group, and diagnostic group, and sample size counts for measures for which sampling is performed. As noted above, we are proposing five new measures beginning with the FY 2018 payment determination. However, because, as further described above, we are eliminating reporting this non-measure data by quarter for all measures, we believe that the addition of five measures leads to a net negligible change in burden associated with non-measure data collection.

*C. Summary of Annual Burden Estimates for Proposed Requirements*

TABLE 25—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS UNDER OMB CONTROL NUMBER 0938–1171 (CMS–10432)

| Preamble section(s) | Proposed action | Respondents | Responses (per respondent) | Burden per response (hours)* | Total annual burden (hours) | Labor cost of reporting ($/hr) | Total cost ($) |
|---|---|---|---|---|---|---|---|
| V.C. | Remove HBIPS–4 | 1,617 | 862 (431 cases/yr × 2 measures). | 0.20 | 278,770.80 | 22.37 | 6,236,102.80 |
| V. | Remove HBIPS–6 and HBIPS–7. | | | | | | |
| V. | Add NQF # 1656, # 1663, # 0647, # 0648, and Screening for Metabolic Disorders. | | | | | | |
| | Training | | 1 | 2 | 3,234 | | 72,344.58 |
| Total | | 1,617 | 863 | 2.2 | 282,004.8 | 22.37 | 6,308,447.38 |

*D. ICRs Regarding the Hospital and Health Care Complex Cost Report (CMS–2552–10)*

This rule would not impose any new or revised collection of information requirements associated with CMS–2552–10 (as discussed under preamble section III.A.3.a.i.). Consequently, the cost report does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The report's information collection requirements and burden estimates are approved by OMB under control number 0938–0052.

*E. Submission of PRA-Related Comments*

We submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at *www.cms.hhs.gov/Paperwork@cms.hhs.gov*, or call the Reports Clearance Office at 410–786–1326.

We invite public comment on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified under the **ADDRESSES** caption of this proposed rule and identify the rule (CMS–1627–P).

PRA-related comments must be received on/by June 23, 2015.

## VII. Regulatory Impact Analysis

*A. Statement of Need*

This proposed rule would update the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during the FY beginning October 1, 2015, through September 30, 2016. We are applying the proposed FY 2012-based IPF-specific market basket increase of 2.7 percent, less the productivity adjustment of 0.6 percentage point as required by 1886(s)(2)(A)(i) of the Act, and further reduced by 0.2 percentage point as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(D) of the Act. In this proposed rule, we propose to adopt an IPF-specific market basket and to update the IPF labor-related share; to adopt new OMB CBSA delineations for the FY 2016 IPF Wage Index; and to phase out the rural adjustment for 37 rural providers which would become urban providers as a result of the new CBSA delineations. Additionally, this rule reminds providers of the October 1, 2015 implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–

[70] In the FY 2015 IPF PPS final rule we estimated 1,626 IPFs and are adjusting that estimate by −9 to account for more recent data.

[71] In the FY 2015 IPF PPS final rule we estimated 556 cases per year and are adjusting that estimate by −125 to account for more recent data.

10–CM/PCS) for the IPF prospective payment system, updates providers on the status of IPF PPS refinements, and proposes new quality reporting requirements for the IPFQR Program.

*B. Overall Impact*

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for a major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is not designated as economically ''significant'' under section 3(f)(1) of Executive Order 12866.

We estimate that the total impact of these changes for FY 2016 payments compared to FY 2015 payments will be a net increase of approximately $80 million. This reflects a $95 million increase from the update to the payment rates, as well as a $15 million decrease as a result of the update to the outlier threshold amount. Outlier payments are estimated to decrease from 2.3 percent in FY 2015 to 2.0 percent of total IPF payments in FY 2016.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of $7.5 million to $38.5 million or less in any 1 year, depending on industry classification (for details, refer to the SBA Small Business Size Standards found at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*), or being nonprofit organizations that are not dominant in their markets.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs' revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA.

As shown in Table 26, we estimate that the overall revenue impact of this proposed rule on all IPFs is to increase Medicare payments by approximately 1.6 percent. As a result, since the estimated impact of this proposed rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this proposed rule would have a positive revenue impact on a substantial number of small entities. MACs are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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 an adverse impact on the rural hospitals based on the data of the 275 rural units and 68 rural hospitals in our database of 1,617 IPFs for which data were available. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This proposed rule will not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of $144 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. As stated above, this proposed rule would not have a substantial effect on state and local governments.

*C. Anticipated Effects*

We discuss the historical background of the IPF PPS and the impact of this proposed rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and May 2006 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT rate to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. The budget neutrality factor includes the following components: outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the May 2008 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section III.D.1.e. of this proposed rule, we are using the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem base rate and ECT rate. Therefore, the budgetary impact to the Medicare program of this proposed rule will be due to the estimated market basket update for FY 2016 of 2.7 percent (see section III.A.4. of this proposed rule) less the productivity adjustment of 0.6 percentage point required by section 1886 (s)(2)(A)(i) of the Act; further reduced by the ''other adjustment'' of 0.2 percentage point under sections 1886(s)(2)(A)(ii) and 1886 (s)(3)(D) of the Act; and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2016 impact will be a net increase of $80 million in payments to IPF providers. This reflects an estimated $95 million increase from the update to the payment rates and a $15 million decrease due to the update to the outlier threshold amount to set total estimated outlier payments at 2.0 percent of total estimated payments in FY 2016. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section VII.C.4. below).

2. Impact on Providers

To understand the impact of the changes to the IPF PPS on providers, discussed in this proposed rule, it is necessary to compare estimated payments under the IPF PPS rates and factors for FY 2016 versus those under FY 2015. We determined the percent change of estimated FY 2016 IPF PPS payments to FY 2015 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the updated wage index data; the changes to wage index CBSAs; the changes to rural adjustment payments resulting from changes in rural or urban status, due to CBSA changes; the proposed labor-related share; and the estimated market basket update for FY 2016, as adjusted by the productivity adjustment according to section 1886(s)(2)(A)(i), and the ''other adjustment'' according to sections 1886(s)(2)(A)(ii) and 1886(s)(3)(D) of the Act.

To illustrate the impacts of the FY 2016 changes in this proposed rule, our analysis begins with a FY 2015 baseline simulation model based on FY 2014 IPF payments inflated to the midpoint of FY 2015 using IHS Global Insight Inc.'s most recent forecast of the market basket update (see section III.A.4. of this proposed rule); the estimated outlier payments in FY 2015; the CBSA delineations for IPFs based on OMB's MSA definitions after June 2003; the FY 2014 pre-floor, pre-reclassified hospital wage index; the FY 2015 labor-related share; and the FY 2015 percentage amount of the rural adjustment. During the simulation, the total estimated outlier payments are maintained at 2 percent of total IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The update to the outlier fixed dollar loss threshold amount;
- The FY 2015 pre-floor, pre-reclassified hospital wage index without the revised OMB delineations;
- The FY 2015 updated CBSA delineations, based on OMB's February 28, 2013 Bulletin No. 13–01, as described in section III.D.1.c. of this proposed rule, with the proposed blended FY 2016 IPF wage index;
- The FY 2016 rural adjustment, accounting for changes to rural or urban status due to the updated CBSA delineations, including the phase-out of the rural adjustment for the IPFs changing from rural to urban status, as described in section III.D.1.d;
- The proposed FY 2016 labor-related share;
- The estimated market basket update for FY 2016 of 2.7 percent less the productivity adjustment of 0.6 percentage point reduction in accordance with section 1886(s)(2)(A)(i) of the Act and further reduced by the ''other adjustment'' of 0.2 percentage point in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(D) of the Act.

Our final comparison illustrates the percent change in payments from FY 2015 (that is, October 1, 2014, to September 30, 2015) to FY 2016 (that is, October 1, 2015, to September 30, 2016) including all the changes in this proposed rule.

TABLE 26—IPF IMPACT TABLE FOR FY 2016

[% change in columns 3–9]

| Facility by type | Number of IPFs | Outlier | Wage index [1] | CBSA [2] | Change in rural adjustment [3] | Labor related share (74.9%) [4] | IPF market basket update [5] | Total percent change [6] |
|---|---|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) |
| All Facilities | 1,617 | −0.3 | 0.0 | 0.0 | 0.0 | 0.0 | 1.9 | 1.6 |
| Total Urban | 1,274 | −0.3 | 0.0 | 0.0 | 0.0 | 0.2 | 1.9 | 1.8 |
| Total Rural | 343 | −0.3 | 0.0 | −0.2 | 0.2 | −1.1 | 1.9 | 0.6 |
| Urban unit | 847 | −0.4 | 0.0 | 0.0 | 0.0 | 0.2 | 1.9 | 1.7 |
| Urban hospital | 427 | −0.1 | −0.1 | 0.1 | 0.0 | 0.1 | 1.9 | 1.9 |
| Rural unit | 275 | −0.3 | 0.1 | −0.2 | 0.2 | −1.1 | 1.9 | 0.5 |
| Rural hospital | 68 | −0.1 | 0.0 | −0.3 | 0.2 | −1.0 | 1.9 | 0.7 |
| CBSA Change: | | | | | | | | |
| Urban to Urban | 1,237 | −0.3 | 0.0 | 0.0 | 0.1 | 0.2 | 1.9 | 1.8 |
| Rural to Rural | 340 | −0.3 | 0.0 | −0.2 | 0.1 | −1.1 | 1.9 | 0.4 |
| Urban to Rural | 3 | −0.1 | 3.1 | −0.4 | 16.2 | −1.1 | 1.9 | 20.1 |
| Rural to Urban | 37 | −0.2 | 0.1 | 2.8 | −4.1 | −0.9 | 1.9 | −0.5 |
| By Type of Ownership: | | | | | | | | |
| Freestanding IPFs: | | | | | | | | |
| Urban Psychiatric Hospitals: | | | | | | | | |
| Government | 123 | −0.3 | 0.1 | 0.0 | 0.0 | 0.1 | 1.9 | 1.8 |
| Non-Profit | 99 | −0.1 | 0.4 | 0.1 | 0.0 | 0.4 | 1.9 | 2.7 |
| For-Profit | 205 | 0.0 | −0.3 | 0.1 | 0.0 | 0.0 | 1.9 | 1.6 |
| Rural Psychiatric Hospitals: | | | | | | | | |
| Government | 36 | −0.1 | 0.2 | −0.1 | 0.4 | −0.8 | 1.9 | 1.5 |
| Non-Profit | 11 | −0.5 | −0.6 | 0.0 | 0.0 | −0.3 | 1.9 | 0.5 |
| For-Profit | 21 | 0.0 | 0.0 | −0.6 | 0.1 | −1.3 | 1.9 | 0.1 |
| IPF Units: | | | | | | | | |
| Urban: | | | | | | | | |
| Government | 129 | −0.6 | −0.2 | −0.1 | 0.0 | 0.3 | 1.9 | 1.2 |
| Non-Profit | 552 | −0.4 | 0.2 | 0.0 | −0.1 | 0.3 | 1.9 | 1.9 |
| For-Profit | 166 | −0.3 | −0.2 | 0.0 | 0.0 | 0.0 | 1.9 | 1.3 |
| Rural: | | | | | | | | |
| Government | 69 | −0.2 | −0.1 | −0.3 | 0.1 | −1.3 | 1.9 | 0.0 |
| Non-Profit | 142 | −0.3 | 0.2 | −0.2 | 0.3 | −0.9 | 1.9 | 0.8 |
| For-Profit | 64 | −0.3 | 0.0 | −0.2 | 0.2 | −1.2 | 1.9 | 0.3 |
| By Teaching Status: | | | | | | | | |
| Non-teaching | 1,420 | −0.2 | −0.1 | 0.0 | 0.0 | −0.1 | 1.9 | 1.5 |
| Less than 10% interns and residents to beds | 110 | −0.3 | 0.2 | −0.1 | 0.0 | 0.5 | 1.9 | 2.1 |
| 10% to 30% interns and residents to beds | 61 | −0.7 | 0.4 | −0.1 | 0.0 | 0.5 | 1.9 | 2.1 |
| More than 30% interns and residents to beds | 26 | −0.7 | 0.4 | 0.0 | 0.0 | 0.8 | 1.9 | 2.4 |

TABLE 26—IPF IMPACT TABLE FOR FY 2016—Continued

[% change in columns 3–9]

| Facility by type | Number of IPFs | Outlier | Wage index [1] | CBSA [2] | Change in rural adjustment [3] | Labor related share (74.9%) [4] | IPF market basket update [5] | Total percent change [6] |
|---|---|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) |
| By Region: | | | | | | | | |
| New England | 108 | −0.3 | 0.8 | 0.0 | 0.0 | 0.7 | 1.9 | 3.2 |
| Mid-Atlantic | 243 | −0.2 | 0.2 | −0.1 | 0.0 | 0.6 | 1.9 | 2.4 |
| South Atlantic | 238 | −0.2 | −0.3 | 0.1 | −0.1 | −0.4 | 1.9 | 0.9 |
| East North Central | 259 | −0.2 | 0.0 | 0.0 | 0.1 | −0.2 | 1.9 | 1.6 |
| East South Central | 160 | −0.2 | −0.5 | 0.0 | −0.1 | −1.1 | 1.9 | 0.0 |
| West North Central | 141 | −0.4 | 0.0 | 0.1 | 0.0 | −0.3 | 1.9 | 1.3 |
| West South Central | 243 | −0.2 | −0.5 | 0.0 | −0.1 | −0.7 | 1.9 | 0.3 |
| Mountain | 103 | −0.2 | 0.4 | 0.0 | 0.1 | 0.2 | 1.9 | 2.3 |
| Pacific | 122 | −0.4 | 0.5 | 0.0 | 0.1 | 1.3 | 1.9 | 3.4 |
| By Bed Size: | | | | | | | | |
| Psychiatric Hospitals: | | | | | | | | |
| Beds: 0–24 | 83 | −0.1 | 0.0 | 0.1 | −0.3 | −0.7 | 1.9 | 0.8 |
| Beds: 25–49 | 77 | −0.1 | −0.4 | 0.3 | −0.1 | −0.2 | 1.9 | 1.4 |
| Beds: 50–75 | 84 | −0.1 | 0.0 | 0.0 | 0.1 | 0.0 | 1.9 | 1.9 |
| Beds: 76 + | 251 | −0.1 | 0.0 | 0.0 | 0.0 | 0.1 | 1.9 | 2.0 |
| Psychiatric Units: | | | | | | | | |
| Beds: 0–24 | 662 | −0.4 | 0.0 | 0.0 | 0.0 | −0.3 | 1.9 | 1.2 |
| Beds: 25–49 | 301 | −0.4 | 0.0 | 0.1 | 0.0 | 0.0 | 1.9 | 1.7 |
| Beds: 50–75 | 103 | −0.3 | 0.1 | 0.0 | 0.0 | 0.1 | 1.9 | 1.9 |
| Beds: 76 + | 56 | −0.4 | −0.1 | −0.2 | 0.0 | 0.5 | 1.9 | 1.7 |

[1] Includes a FY 2016 IPF wage index, current CBSA delineations, and a labor-related share of 0.69294.

[2] Includes a 50/50 FY 2016 proposed blended IPF wage index, new CBSA delineations, and a labor-related share of 0.69294.

[3] Includes a 50/50 FY 2016 proposed blended IPF wage index, new CBSA delineations, a labor-related share of 0.69294, and a rural adjustment. Providers changing from urban to rural status will receive a 17 percent rural adjustment, and providers changing from rural to urban status will receive 2/3 of the 17 percent rural adjustment in FY 2016. For those changing from urban to rural status, the total impact shown is affected by outlier threshold increasing, which results in smaller outlier payments as part of total payments. For those changing from rural to urban status, the outlier threshold is being lowered by 2/3 of 17 percent, which results in more providers being eligible for outlier payments, increasing the outlier portion of their total payments.

[4] Includes a 50/50 FY 2016 proposed blended IPF wage index, new CBSA delineations, a labor-related share of 0.749, and a rural adjustment.

[5] This column reflects the payment update impact of the IPF-specific market basket update of 2.7 percent, a 0.6 percentage point reduction for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(D) of the Act.

[6] Percent changes in estimated payments from FY 2015 to FY 2016 include all of the changes presented in this proposed rule. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

3. Results

Table 26 above displays the results of our analysis. The table groups IPFs into the categories listed below based on characteristics provided in the Provider of Services (POS) file, the IPF provider specific file, and cost report data from HCRIS:

- Facility Type
- Location
- Teaching Status Adjustment
- Census Region
- Size

The top row of the table shows the overall impact on the 1,617 IPFs included in this analysis.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 2.3 percent in FY 2015. Thus, we are adjusting the outlier threshold amount in this proposed rule to set total estimated outlier payments equal to 2 percent of total payments in FY 2016. The estimated change in total IPF payments for FY 2016, therefore, includes an approximate 0.3 percent decrease in payments because the outlier portion of total payments is expected to decrease from approximately 2.3 percent to 2.0 percent.

The overall impact of this outlier adjustment update (as shown in column 3 of Table 26), across all hospital groups, is to decrease total estimated payments to IPFs by 0.3 percent. The largest decrease in payments is estimated to reflect a 0.7 percent decrease in payments for IPFs located in teaching hospitals with an intern and resident Average Daily Census (ADC) ratio that is 10 percent or greater.

In column 4, we present the effects of the budget-neutral proposed update to the IPF wage index. This represents the effect of using the most recent wage data available without taking into account the revised OMB delineations, which are presented separately in the next column. That is, the impact represented in this column is solely that of updating from the FY 2015 IPF wage index to the FY 2016 IPF wage index without any changes to the OMB delineations. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4. However, there will be distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 3.1 percent for IPFs changing from urban to rural status, and the largest decrease in payments to be 0.6 percent for rural non-profit freestanding IPFs.

In column 5, we present the effects of the new OMB delineations and the proposed transition to the new delineations using the transitional IPF wage index. The FY 2016 IPF proposed transitional wage index is a blended wage index using 50 percent of the IPF's FY 2016 wage index based on the new OMB delineations and 50 percent of the IPF's FY 2016 wage index based on the OMB delineations used in FY 2015. In the aggregate, since these proposed updates to the wage index are applied in a budget-neutral manner, we do not estimate that these proposed updates would affect overall estimated payments to IPFs. However, we estimate that these proposed updates would have distributional effects. We estimate the largest increase in payments would be 2.8 percent for IPFs changing from rural to urban status and the largest decrease in payments would be 0.6 percent for rural for-profit freestanding IPFs.

In column 6, we present the effects of the changes to the rural adjustment under the new CBSA delineations. There are 3 urban IPFs which would be

newly designated as rural IPFs, which would now receive a full 17 percent rural adjustment. We estimate that the largest increase in payments would be to these 3 newly-rural IPFs. Note that each column's simulations include both regular and outlier payments; as regular payments increase, outlier payments decrease to maintain outlier payments at 2 percent of total payments. As such, the increase to total IPF payments is estimated to be 16.2 percent. There are also 37 rural IPFs which would be newly designated as urban IPFs, where we proposed to phase out their rural adjustment over 3 years. These 37 newly-urban providers would receive ⅔ of the 17 percent rural adjustment in FY 2016, ⅓ of the 17 percent rural adjustment in FY 2017, and no rural adjustment for FY 2018 and subsequent years. As the regular payments for these 37 providers decrease, their outlier payments increase to maintain outlier payments at 2 percent of total payments. We estimate that the largest decrease in payments would be 4.1 percent for these 37 newly-urban providers.

In column 7, we present the estimated effects of the proposed labor-related share. The proposed update to the IPF labor-related share is made in a budget-neutral manner and therefore would not affect total estimated IPF PPS payments. However, it would affect the estimated distribution of payments among providers. For example, we estimate the largest increase in payments would be 1.3 percent to IPFs in the Pacific region. We estimate the largest decrease in payments would be 1.3 percent to rural for-profit freestanding IPFs and to rural IPF governmental units.

In column 8, we present the estimated effects of the update to the IPF PPS payment rates of 1.9 percent, which are based on a proposed 2.7 percent IPF-specific market basket update, less the productivity adjustment of 0.6 percentage point in accordance with section 1886(s)(2)(A)(i), and further reduced by 0.2 percentage point in accordance with section 1886(s)(2)(A)(ii) and 1886(s)(3)(D).

Finally, column 9 compares our estimates of the total changes reflected in this proposed rule for FY 2016 to the payments for FY 2015 (without these changes). This column reflects all proposed FY 2016 changes relative to FY 2015. The average estimated increase for all IPFs is approximately 1.6 percent. This estimated net increase includes the effects of the estimated 2.7 percent market basket update reduced by the productivity adjustment of 0.6 percentage point, as required by section 1886(s)(2)(A)(i) of the Act and further reduced by the ''other adjustment'' of 0.2 percentage point, as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(D) of the Act. It also includes the overall estimated 0.3 percent decrease in estimated IPF outlier payments as a percent of total payments from the update to the outlier fixed dollar loss threshold amount. Since we are making the updates noted in columns 4 through 7 in a budget-neutral manner, they will not affect total estimated IPF payments in the aggregate. However, they will affect the estimated distribution of payments among providers.

Overall, urban IPFs are estimated to experience a 1.8 percent increase in payments in FY 2016 and rural IPFs are estimated to experience a 0.6 percent increase in payments in FY 2016. The largest estimated decrease in payments is 0.5 percent for rural IPFs that transition to urban status as a result of the new OMB delineations. As noted previously, we proposed to mitigate the effects of the loss of the rural adjustment to these 37 providers by phasing the adjustment out over 3 years. The largest payment increase is estimated at 20.1 percent for IPFs that transition from urban to rural status (thereby gaining the 17 percent rural adjustment), followed by a 3.4 percent increase for IPFs in the Pacific region.

4. Effects of Updates to the IPFQR Program

As discussed in section V. of this proposed rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will implement a 2 percentage point reduction in the FY 2018 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2018, including reporting on the required measures. In section V. of this proposed rule, we discuss how the 2 percentage point reduction will be applied. For FY 2015, of the 1,725 IPFs eligible for the IPFQR Program, 31 IPFs (1.8 percent) did not receive the full market basket update because of the IPFQR Program; 10 of these IPFs chose not to participate and 21 did not meet the requirements of the program. We anticipate that even fewer IPFs would receive the reduction for FY 2016 as IPFs become more familiar with the requirements. Thus, we estimate that this policy will have a negligible impact on overall IPF payments for FY 2016.

Based on the proposals made in this rule, we estimate a total increase in burden of 174.4 hours per IPF or 282,004.80 hours across all IPFs, resulting in a total increase in financial burden of $3,901.33 per IPF or $6,308,447.38 across all IPFs. As discussed in section VI. of this proposed rule, we will attribute the costs associated with the proposals to the year in which these costs begin; for the purposes of all the proposals in this proposed rule, that year is FY 2016. Further information on these estimates can be found in section VI. of this proposed rule.

We intend to closely monitor the effects of this quality reporting program on IPFs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

5. Effect on Beneficiaries

Under the IPF PPS, IPFs will receive payment based on the average resources consumed by patients for each day. We do not expect changes in the quality of care or access to services for Medicare beneficiaries under the FY 2016 IPF PPS, but we continue to expect that paying prospectively for IPF services would enhance the efficiency of the Medicare program.

*D. Alternatives Considered*

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. Therefore, we are updating the IPF PPS using the methodology published in the November 2004 IPF PPS final rule, but with a proposed IPF-specific market basket, and updated labor-related share, a proposed transitional wage index to implement new OMB CBSA designations, and a proposed phase-out of the rural adjustment for the 37 providers changing from rural to urban status as a result of the updated OMB CBSA delineations used in the FY 2016 IPF PPS transitional wage index. We considered implementing the new OMB designations for the FY 2016 IPF PPS wage index without a blend, but wanted to mitigate any negative effects of CBSA changes on IPFs. Additionally, we considered abruptly ending the rural adjustment for the 37 IPF providers which changed from rural to urban status as a result of the OMB CBSA changes. However, we wanted to propose relief from the effects of OMB's new CBSA delineations to the 37 providers which changed from rural to urban status. We also considered whether to allow a phase-in of the updated LRS, but decided that the impact of full implementation did not warrant a phase-in, especially given that we also proposed a transitional wage index and a phase-out of the rural adjustment for those IPFs which changed status from rural to urban under the new CBSAs. Additionally, for

the IPFQR Program, alternatives were not considered because the Program, as designed, best achieves quality reporting goals for the inpatient psychiatric care setting, while minimizing associated reporting burdens on IPFs. Section V. of this proposed rule discusses other benefits and objectives of the Program.

*E. Accounting Statement*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 27 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. The costs for data submission presented in Table 27 are calculated in section VI, which also discusses the benefits of data collection. This table provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this proposed rule and based on the data for 1,617 IPFs in our database. Furthermore, we present the estimated costs associated with updating the IPFQR program. The increases in Medicare payments are classified as Federal transfers to IPF Medicare providers.

TABLE 27—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

| Change in Estimated Transfers From FY 2015 IPF PPS to FY 2016 IPF PPS: | |
|---|---|
| Category | Transfers |
| Annualized Monetized Transfers. | $80 million. |
| From Whom to Whom?. | Federal Government to IPF Medicare Providers. |

TABLE 27—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES—Continued

| Change in Estimated Transfers From FY 2015 IPF PPS to FY 2016 IPF PPS: | |
|---|---|
| Category | Transfers |
| FY 2016 Costs to Updating the Quality Reporting Program for IPFs: | |
| Category | Costs |
| Annualized Monetized Costs for IPFs to Submit Data (Quality Reporting Program) | $6.31 million. |

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 and Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

## PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

■ 2. Section 412.428 is amended by revising paragraph (e) to read as follows:

**§ 412.428 Publication of Updates to the inpatient psychiatric facility prospective payment system.**

* * * * *

(e) Describe the ICD–10–CM coding changes and DRG classification changes discussed in the annual update to the hospital inpatient prospective payment system regulations.

* * * * *

Dated: April 13, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: April 22, 2015.

**Sylvia M. Burwell,**

*Secretary.*

**Note:** The following addendum will not publish in the Code of Federal Regulations.

**Addendum—FY 2016 Proposed Rates and Adjustment Factors**

Per Diem Rate:

| | |
|---|---|
| Federal Per Diem Base Rate | $745.19 |
| Labor Share (0.749) | 558.15 |
| Non-Labor Share (0.251) | 187.04 |

Per Diem Rate Applying the 2 Percentage Point Reduction

| | |
|---|---|
| Federal Per Diem Base Rate | $730.56 |
| Labor Share (0.749) | 547.19 |
| Non-Labor Share (0.251) | 183.37 |

Fixed Dollar Loss Threshold Amount: $9,825.

Wage Index Budget-Neutrality Factor: 1.0041.

Facility Adjustments:

| | |
|---|---|
| Rural Adjustment Factor. | 1.17 |
| Teaching Adjustment Factor. | 0.5150 |
| Wage Index | Pre-reclass Hospital Wage Index (FY2015) |

*Cost of Living Adjustments (COLAs):*

| Area | Cost of living adjustment factor |
|---|---|
| Alaska: | |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 1.23 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 1.23 |
| Rest of Alaska | 1.25 |
| Hawaii: | |
| City and County of Honolulu | 1.25 |
| County of Hawaii | 1.19 |
| County of Kauai | 1.25 |
| County of Maui and County of Kalawao | 1.25 |

*Patient Adjustments:*

| | |
|---|---|
| ECT—Per Treatment | $320.82 |
| ECT—Per Treatment Applying the 2 Percentage Point Reduction | 314.52 |

*Variable Per Diem Adjustments:*

| | Adjustment factor |
|---|---|
| Day 1—Facility Without a Qualifying Emergency Department | 1.19 |
| Day 1—Facility With a Qualifying Emergency Department | 1.31 |
| Day 2 | 1.12 |
| Day 3 | 1.08 |
| Day 4 | 1.05 |
| Day 5 | 1.04 |
| Day 6 | 1.02 |
| Day 7 | 1.01 |
| Day 8 | 1.01 |
| Day 9 | 1.00 |
| Day 10 | 1.00 |
| Day 11 | 0.99 |
| Day 12 | 0.99 |
| Day 13 | 0.99 |
| Day 14 | 0.99 |
| Day 15 | 0.98 |
| Day 16 | 0.97 |
| Day 17 | 0.97 |
| Day 18 | 0.96 |
| Day 19 | 0.95 |
| Day 20 | 0.95 |
| Day 21 | 0.95 |
| After Day 21 | 0.92 |

*Age Adjustments:*

| Age (in years) | Adjustment factor |
|---|---|
| *Under 45* | 1.00 |
| 45 and under 50 | 1.01 |
| 50 and under 55 | 1.02 |
| 55 and under 60 | 1.04 |
| 60 and under 65 | 1.07 |
| 65 and under 70 | 1.10 |
| 70 and under 75 | 1.13 |
| 75 and under 80 | 1.15 |
| 80 and over | 1.17 |

*DRG Adjustments:*

| MS–DRG | MS–DRG descriptions | Adjustment factor |
|---|---|---|
| 056 | Degenerative nervous system disorders w MCC | 1.05 |
| 057 | Degenerative nervous system disorders w/o MCC | |
| 080 | Nontraumatic stupor & coma w MCC | 1.07 |
| 081 | Nontraumatic stupor & coma w/o MCC | |
| 876 | O.R. procedure w principal diagnoses of mental illness | 1.22 |
| 880 | Acute adjustment reaction & psychosocial dysfunction | 1.05 |
| 881 | Depressive neuroses | 0.99 |
| 882 | Neuroses except depressive | 1.02 |
| 883 | Disorders of personality & impulse control | 1.02 |
| 884 | Organic disturbances & mental retardation | 1.03 |
| 885 | Psychoses | 1.00 |
| 886 | Behavioral & developmental disorders | 0.99 |
| 887 | Other mental disorder diagnoses | 0.92 |
| 894 | Alcohol/drug abuse or dependence, left AMA | 0.97 |
| 895 | Alcohol/drug abuse or dependence w rehabilitation therapy | 1.02 |
| 896 | Alcohol/drug abuse or dependence w/o rehabilitation therapy w MCC | 0.88 |
| 897 | Alcohol/drug abuse or dependence w/o rehabilitation therapy w/o MCC | |

*Comorbidity Adjustments:*

| Comorbidity | Adjustment factor |
|---|---|
| Developmental Disabilities | 1.04 |
| Coagulation Factor Deficit | 1.13 |

| Comorbidity | Adjustment factor |
|---|---|
| Tracheostomy | 1.06 |
| Eating and Conduct Disorders | 1.12 |
| Infectious Diseases | 1.07 |
| Renal Failure, Acute | 1.11 |
| Renal Failure, Chronic | 1.11 |
| Oncology Treatment | 1.07 |
| Uncontrolled Diabetes Mellitus | 1.05 |
| Severe Protein Malnutrition | 1.13 |
| Drug/Alcohol Induced Mental Disorders | 1.03 |
| Cardiac Conditions | 1.11 |
| Gangrene | 1.10 |
| Chronic Obstructive Pulmonary Disease | 1.12 |
| Artificial Openings—Digestive & Urinary | 1.08 |
| Severe Musculoskeletal & Connective Tissue Diseases | 1.09 |
| Poisoning | 1.11 |

[FR Doc. 2015–09880 Filed 4–24–15; 4:15 pm]

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Part III

## Environmental Protection Agency

40 CFR Part 49

General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country for Five Source Categories; Final Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 49**

**[EPA–HQ–OAR–2011–0151; FRL–9919–85–OAR]**

**RIN 2060–AQ95**

## General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country for Five Source Categories

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is finalizing general permits for use in Indian country pursuant to the Federal Minor New Source Review (NSR) Program in Indian Country for new or modified minor sources in the following two source categories: Hot mix asphalt (HMA) plants; and stone quarrying, crushing, and screening (SQCS) facilities. The EPA is also finalizing permits by rule for use in Indian country for new or modified minor sources in three source categories: Auto body repair and miscellaneous surface coating operations; gasoline dispensing facilities (GDFs), except in California; and petroleum dry cleaning facilities. The EPA is also taking final action authorizing the use of general permits established under the program to create synthetic minor sources for the HMA and SQCS source categories.

**DATES:** The final rule is effective on June 1, 2015.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2011–0151. All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, the EPA/DC, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

**FOR FURTHER INFORMATION CONTACT:** Christopher Stoneman, Outreach and Information Division, Office of Air Quality Planning and Standards, (C–304–03), Environmental Protection Agency, Research Triangle Park, North Carolina, 27711, telephone number (919) 541–0823, facsimile number (919) 541–0072, email address: *stoneman.chris@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Throughout this document, ''reviewing authority,'' ''we,'' ''us'' and ''our'' refer to the EPA. The information in this preamble is organized as follows:

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## I. General Information

### *A. Does this action apply to me?*

Entities potentially affected by this final action consist of owners and operators of facilities included in the following source categories that are located, or planning to locate, in Indian country as defined in 18 U.S.C. 1151 where there is no EPA-approved program in place and that are subject to the requirements of the program:

TABLE 1—SOURCE CATEGORIES

| Industry category | North American Industry Classification System | Examples of regulated entities |
|---|---|---|
| HMA Facilities | 324122 | Asphalt Shingles and Coating Materials Manufacturing. |
| | 324121 | Asphalt Paving Mixture and Block Manufacturing. |
| SQCS Facilities | 212311 | Dimension Stone Mining and Quarrying. |
| | 212312 | Crushed and Broken Limestone Mining and Quarrying. |
| | 212313 | Crushed and Broken Granite Mining and Quarrying. |
| | 212319 | Other Crushed and Broken Stone Mining and Quarrying. |
| | 212321 | Construction Sand and Gravel Mining. |
| Auto Body Repair and Miscellaneous Surface Coating Operations. | 811121 | Automotive Body, Paint, and Interior Repair and Maintenance. |
| | 332812 | Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers. |

TABLE 1—SOURCE CATEGORIES—Continued

| Industry category | North American Industry Classification System | Examples of regulated entities |
|---|---|---|
| GDFs | 4471 | Gasoline Stations. |
| | 44711 | Gasoline Stations without Convenience Stores. |
| | 447110 | Gasoline Stations with Convenience Stores. |
| | 44719 | Other Gasoline Stations. |
| | 447190 | Other Gasoline Stations. |
| Petroleum Dry Cleaning Facilities | 812320 | Dry Cleaning and Laundry Services (Except Coin-Operated). |
| | 812310 | Coin-Operated Laundries and Dry Cleaners. |

This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be potentially affected by this action. To determine whether your facility could be affected by this action, you should examine the applicability criteria in the final federal minor NSR program for Indian country, 40 CFR 49.153. If you have any questions regarding the applicability of this action to a particular entity, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

*B. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this final rule is posted in the regulations and standards section of our NSR home page located at *http://www.epa.gov/nsr* and on the tribal NSR page at *http://www.epa.gov/air/tribal/tribalnsr.html.*

## II. Overview of the Final Rule

In July 2011, the EPA issued the Federal Minor New Source Review Program in Indian Country rule [1] (the Federal Indian Country Minor NSR rule or Rule) that established, among other things, the requirements and process for the preconstruction permitting of minor sources in Indian country. Under the Rule, existing true minor sources were required to register with the EPA by March 1, 2013. True minor sources that commence construction after the Rule's effective date must also register within certain timeframes spelled out in the Rule (40 CFR 49.160). In addition, beginning September 2, 2014, an owner or operator must obtain a preconstruction permit from the reviewing authority [2] if the owner/operator will construct a new true minor source,[3] will modify an existing true minor source in Indian country, or will modify an existing major source in Indian country. In addition, existing synthetic minor sources [4] beginning construction of minor modifications were required to obtain preconstruction permits under the rule beginning August 30, 2011. The rule also specified the process and requirements for using general permits as a streamlined permitting approach to authorize construction and modifications at true minor sources. General permits streamline the preconstruction permitting of new or modified true minor sources because they involve the issuance of one permit that can apply to multiple stationary sources that have similar emissions units.

In today's action, the EPA is finalizing the use of two types of minor NSR preconstruction permits to help streamline the EPA's permitting of true minor sources—and synthetic minor sources in select source categories—that construct or modify in Indian country and belong to one of five different source categories. The first type of permit is a general permit. The second type is a permit by rule, which is another mechanism for streamlining the issuance of preconstruction permits. Permits by rule use a regulatory-type structure (*i.e.,* the permit requirements are codified in the Code of Federal Regulations) to permit sources by pre-authorizing construction and modification activities carried out in accordance with the codified requirements. To become covered by a permit by rule, as we are finalizing today, a source must notify the EPA that it meets the terms of coverage and is complying with the permit's terms and conditions but does not need approval of a Request for Coverage. The source must also submit its Notification of Coverage Form in fulfillment of the minor source registration requirement in the Federal Indian Country Minor NSR rule (40 CFR 49.160(c)(1)(iii)). Once it has done so and the reviewing authority has posted the Notification of Coverage Form online, the source may commence construction of a new source or modification of an existing source.

In this final action, we are finalizing general permits for HMA plants and SQCS facilities. We are finalizing permits by rule for GDFs (except for California), auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities.[5] For permits by rule, we are finalizing the regulatory framework via rulemaking that: (a) Defines a permit by rule; (b) explains how we will issue them; (c) describes the process for granting coverage; and (d) provides the general and specific permit terms and conditions. For all of the permits we are finalizing today, we are providing the following implementation documents and tools: Questionnaires; Instructions; Potential to Emit (PTE) Calculators; and Background Documents. For the general permits we are finalizing today, we are

[1] "Review of New Sources and Modifications in Indian Country," U.S. Environmental Protection Agency, 76 FR 38748, July 1, 2011, *https://www.federalregister.gov/articles/2011/07/01/2011–14981/review-of-new-sources-and-modifications-in-indian-country.*

[2] In this document, reviewing authority refers to an EPA Regional Office. However, tribes can become reviewing authorities if they decide to assist the EPA with implementation of the minor NSR program in their area, and the EPA delegates the authority to assist the EPA to the tribe.

[3] At 40 CFR 49.152(d), true minor source is defined as a source, not including the exempt emissions units and activities listed in § 49.153(c), that emits or has the potential to emit regulated NSR pollutants in amounts that are less than the major source thresholds in § 49.167 (Major NSR program for Nonattainment Areas) or § 52.21 (Prevention of Significant Deterioration program), as applicable, but equal to or greater than the minor NSR thresholds in § 49.153, without the need to take an enforceable restriction to reduce its potential to emit to such levels. The PTE includes fugitive emissions, to the extent that they are quantifiable, only if the source belongs to one of the 28 source categories listed in part 51, Appendix S, paragraph II.A.4(iii) or § 52.21(b)(1)(iii) of 40 CFR, as applicable.

[4] At 40 CFR 49.152(d), synthetic minor source means a source that otherwise has the potential to emit regulated NSR pollutants in amounts that are at or above those for major sources in § 49.167, § 52.21 or § 71.2, as applicable, but that has taken a restriction so that its potential to emit is less than such amounts for major sources. Such restrictions must be enforceable as a practical matter.

[5] The general permits are available online at: *http://www.epa.gov/air/tribal/tribalnsr.html* and at Docket ID No. EPA–HQ–OAR–2011–0151.

providing Request for Coverage Forms (applications). For the permits by rule we are finalizing today, we are providing Notification of Coverage Forms.[6]

In this action, the EPA is also finalizing the use of general permits to create synthetic minor sources for the HMA and SQCS source categories. We have decided to issue final general permits for these two categories (and not the three others) that involve more complex operations and multiple pollutants because the general permit approval process provides an opportunity for case-specific reviewing authority review. Because permits by rule do not provide for the same level of review, the EPA is not finalizing the use of permits by rule to create synthetic minor sources. Finally, in this action we are promulgating three minor amendments to the Federal Indian Country Minor NSR rule. One amendment will allow sources to use a general permit immediately upon the permit becoming final.[7] The second and third amendments ensure that it is clear the permit by rule is an option available to true minor sources that are required to obtain a minor NSR permit.

## III. Background

### *A. Federal Indian Country Minor NSR Rule*

1. What is the Federal Indian Country Minor NSR rule?

On August 21, 2006, the EPA proposed the regulation: ''Review of New Sources and Modifications in Indian Country'' (commonly referred to as the Federal Indian Country NSR rule).[8] Within this proposed regulation, the EPA proposed to protect air quality in Indian country, as defined in 18 U.S.C. 1151, by establishing a federal implementation plan (FIP) program to regulate, among other matters, the modification and construction of minor stationary sources consistent with the requirements of section 110(a)(2)(c) of the Clean Air Act (CAA). We refer to this part of the Federal Indian Country NSR rule as the Federal Indian Country Minor NSR rule. Under the Federal Indian Country Minor NSR rule, we proposed to fill a regulatory gap and provide a mechanism for issuing preconstruction permits for the construction of new minor sources and certain modifications of major and minor sources in Indian country. We promulgated final rules on July 1, 2011,[9] and the FIP became effective on August 30, 2011.

The Federal Indian Country Minor NSR rule applies to new and modified minor stationary sources and to minor modifications at existing major stationary sources located in Indian country[10] where there is no EPA-approved program in place. Tribes can elect to develop and implement their own EPA-approved program under the Tribal Authority Rule,[11] but they are not required to do so.[12] In the absence of an approved tribal program, EPA implements this program. Alternatively, tribes can take delegation of the program from EPA and become the reviewing authority.

Beginning September 2, 2014, any new stationary sources that will emit, or will have the PTE, a regulated NSR pollutant in amounts that will be: (a) Equal to or greater than the minor NSR thresholds, established in the Federal Indian Country Minor NSR rule; and (b) less than the amount that would qualify the source as a major source or a major modification for purposes of the Prevention of Significant Deterioration (PSD) or nonattainment major NSR programs, must apply for and obtain a minor NSR permit before beginning construction of the new source. Likewise, any existing stationary source (minor or major) must apply for and obtain a minor NSR permit before beginning construction of a physical or operational change that will increase the allowable emissions of the stationary source by more than the specified threshold amounts, if the change does not otherwise trigger the permitting requirements of the PSD or nonattainment major NSR program(s).[13]

Among other things, the Federal Indian Country Minor NSR rule created a framework for the EPA to streamline the issuance of preconstruction permits to true minor sources by using general permits.

2. What is a true minor source and how does it differ from a synthetic minor source?

''True minor source,'' under the Federal Indian Country Minor NSR rule means a source that emits, or has the potential to emit, regulated NSR pollutants in amounts that are less than the major source thresholds under either the PSD Program at 40 CFR 52.21, or the Federal Major New Source Review Program for Nonattainment Areas in Indian Country at 40 CFR 49.166–49.173, but equal to or greater than the minor NSR thresholds in § 49.153, without the need to take an enforceable restriction to reduce its PTE to such levels. A source's PTE includes fugitive emissions, to the extent that they are quantifiable, only if the source belongs to one of the 28 source categories listed in part 51, Appendix S, paragraph II.A.4(iii) or § 52.21(b)(1)(iii) of 40 CFR, as applicable. By contrast, ''synthetic minor source'' means a source that otherwise has the potential to emit regulated NSR pollutants in amounts that are at or above those thresholds for major sources, but that has taken a restriction so that its PTE is less than such amounts. Such restrictions must be enforceable as a legal and practical matter.

3. What is a general permit?

A general permit, for purposes of this action, is a permit document that contains standardized requirements that

[6] All of the implementation documents and tools are available online at: *http://www.epa.gov/air/tribal/tribalnsr.html.*

[7] Under the current Rule, a general permit becomes final either when the time for challenging the permit has expired or the review process for challenging a permit has been completed and the permit has been upheld. See 40 CFR 49.159.

[8] ''Review of New Sources and Modifications in Indian Country,'' U.S. Environmental Protection Agency, 71 FR 48696, August 21, 2006, *http://www.gpo.gov/fdsys/pkg/FR-2006-08-21/html/06-6926.htm.*

[9] ''Review of New Sources and Modifications in Indian Country,'' U.S. Environmental Protection Agency, 76 FR 38748, July 1, 2011, *https://www.federalregister.gov/articles/2011/07/01/2011-14981/review-of-new-sources-and-modifications-in-indian-country.*

[10] The Federal Indian Country Minor NSR rule defines ''Indian country'' to include three categories of lands consistent with 18 U.S.C. 1151, *i.e.,* Indian reservations, dependent Indian communities, and Indian allotments. The U.S. Court of Appeals for the District of Columbia Circuit vacated the rule with respect to non-reservation areas of Indian country (*i.e.,* dependent Indian communities and Indian allotments) (*Oklahoma Dept. of Environmental Quality* v. *EPA,* 740 F.3d 185 (D.C. Cir. 2014)). The court held that the state, not tribes or the EPA, has initial primary responsibility for implementation plans under Clean Air Act section 110 in non-reservation areas of Indian country in the absence of a demonstration of tribal jurisdiction by the EPA or a tribe. The rule, therefore, does not apply in non-reservation areas of Indian country unless a tribe or the EPA has demonstrated that a tribe has jurisdiction in a particular non-reservation area of Indian country.

[11] To develop and implement an EPA-approved program, under the Tribal Authority Rule a tribe must meet four requirements: (1) be a federally-recognized tribe, (2) have a functioning government, (3) have the legal authority and (4) have the capacity to run the program. For more information go to: ''Indian Tribes: Air Quality Planning and Management,'' U.S. Environmental Protection Agency, 63 FR 7254, February 12, 1998, *http://www.gpo.gov/fdsys/pkg/FR-1998-02-12/pdf/98-3451.pdf.*

[12] Under tribal law, tribes can also establish permit fees under a tribal permitting program as do most states.

[13] A source may, however, be subject to certain monitoring, recordkeeping and reporting (MRR) requirements under the major NSR programs, if the change has a reasonable possibility of resulting in a major modification. A source may be subject to both the Federal Indian Country Minor NSR rule and the reasonable possibility MRR requirements of the major NSR program(s).

multiple stationary sources can use. The Federal Indian Country Minor NSR rule specified the process and requirements for using general permits to authorize construction and modifications at minor sources as a streamlined permitting approach. The EPA may issue a general permit for categories of emissions units or stationary sources that are similar in nature, have substantially similar emissions, and would be subject to the same or substantially similar permit requirements.[14] ''Similar in nature'' refers to size, processes, and operating conditions. The purpose of a general permit is to provide for protection of air quality while simplifying the permitting process for similar minor sources. General permits offer a cost-effective means of issuing permits and provide a quicker and simpler mechanism for permitting minor sources than the site-specific permitting process.

While the final Federal Indian Country Minor NSR rule contemplated issuance of general permits by the EPA Regional Offices,[15] we have determined (for the permits on which we are taking final action) that a nationwide action is appropriate. Through this action, we are finalizing general permits to serve as preconstruction permit authorizations that contain emission limitations and other restrictions to govern how sources construct, modify and operate.

4. What is a permit by rule?

Like a general permit, a permit by rule is a standard set of requirements that can apply to multiple stationary sources with similar emissions characteristics. For purposes of this action, a permit by rule would differ from a general permit in that the agency would codify a permit by rule directly into the Federal Indian Country Minor NSR rule. The process for a source to gain coverage under a permit by rule is more streamlined compared to a general permit, or a site-specific permit. The permits by rule program establishes a more streamlined notification of coverage process that allows an individual applicant to notify the reviewing authority that it meets the eligibility criteria for the permit and the permit conditions rather than have to go through a reviewing authority review and approval process. This ''notification'' process streamlines permitting for eligible sources and makes it easier for the reviewing authority to implement the permit by rule program compared to traditional site-specific permits and standard general permits.

*B. General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country—Proposed Rule*

1. What was in the proposed rule?

On January 14, 2014 (79 FR 2545), the EPA published a proposed rule, ''General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country,'' to simplify the CAA permitting process for five source categories: HMA plants, SQCS facilities, auto body repair and miscellaneous surface coating operations, GDFs (except in California), and petroleum dry cleaning facilities.[16] The proposed action is intended to ensure that air quality in Indian country is protected by facilitating the implementation of the Federal Indian Country Minor NSR rule issued by the EPA in July 2011.

As the preferred approach, the EPA proposed draft general permits for new or modified minor sources in the following five categories of emission sources: HMA plants, SQCS facilities, GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities. As an alternative approach, we proposed a permit by rule for new or modified minor sources in three of the five source categories: GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities. We also proposed five changes to the following provisions in the Federal Indian Country Minor NSR rule: § 49.151(c)(1)(iii)(B); § 49.156(e); and § 49.160(c)(1)(ii) and (c)(1)(iii). The changes are:

(a) Shortening the general permit application review process from 90 to 45 days for certain source categories;

(b) Adjusting the deadline by which minor sources covered by a general permit need to obtain a preconstruction permit;

(c) Extending the permitting deadline for true minor sources within the oil and gas source category;

(d) Removing a provision to make clear that sources may seek coverage under a general permit as soon as it is effective and need not wait an additional 4 months; and

(e) Adjusting the deadline for oil and gas sources for certain registration-related requirements to be consistent with the proposed permitting deadline extension.

2. Previously Finalized Actions From the January 14, 2014, Proposal

In a final rulemaking dated May 22, 2014, and published June 16, 2014,[17] the EPA amended the Federal Indian Country Minor NSR rule by finalizing the following three actions:

- Adjusted the deadline by which minor sources covered by a general permit need to obtain a preconstruction permit by eliminating a requirement for all true minor sources that begin operation before September 2, 2014, to obtain a minor NSR permit 6 months after the EPA publishes a general permit (no general permits have been finalized to date, so the provision is now moot; item (b) above) (§ 49.151(c)(1)(iii)(B));
- Extended the permitting deadline for true minor sources within the oil and gas source category (item (c) above) (§ 49.151(c)(1)(iii)(B)); and
- Adjusted the deadline for oil and gas sources for certain registration-related requirements to be consistent with the proposed permitting deadline extension (item (e) above) (§ 49.151(c)(1)(iii)(A); § 49.160(c)(1)(ii) and (c)(1)(iii)).

## IV. Final Rulemaking Action

This section outlines the major areas where we sought comment in the January 14, 2014, proposal, highlights our responses and describes our final action in those areas. The complete Response to Comments Document (RTC) can be found in docket EPA–HQ–OAR–2011–0151 and contains more detailed summaries of the comments we received and our responses to them. As noted in Section III. Background, we have already responded to some of the comments made on the January 14, 2014, proposal in the final action we took on May 22, 2014. In addition, as noted below, we will address comments related to the permitting of minor sources in the oil and natural gas sector in the context of the EPA's follow up to

[14] ''Review of New Sources and Modifications in Indian Country,'' U.S. Environmental Protection Agency, 76 FR 38770, July 1, 2011, *https://www.federalregister.gov/articles/2011/07/01/2011-14981/review-of-new-sources-and-modifications-in-indian-country.*

[15] If a tribe develops an EPA-approved implementation plan, then under that plan it could also issue its own general permits.

[16] On July 17, 2014, the EPA published a second proposed rule to simplify the permitting process for six source categories: Concrete batch plants, boilers, stationary spark ignition engines, stationary compression ignition engines, graphic arts and printing operations, and sawmills. This second proposed rule can found at: ''General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country,'' 79 FR 41846, July 17, 2014, *http://www.gpo.gov/fdsys/pkg/FR-2014-07-17/pdf/2014-16814.pdf.* EPA will finalize permits for these six source categories in a separate action.

[17] ''Review of New Sources and Modifications in Indian Country Amendments to the Registration and Permitting Deadlines for True Minor Sources,'' 79 FR 34231, June 16, 2014, *http://www.gpo.gov/fdsys/pkg/FR-2014-06-16/pdf/2014-14030.pdf.*

an Advance Notice of Proposed Rulemaking [18] (ANPR). In the ANPR, we sought feedback on how to address minor source NSR permitting for oil and natural gas sources in Indian country.

*A. Permit Documents and Implementation Tools*

1. Proposed Rule

As our preferred approach, the EPA proposed general permits for use in Indian country pursuant to the Federal Indian Country Minor NSR rule for new or modified minor sources in the following five source categories: HMA plants, SQCS facilities, auto body repair and miscellaneous surface coating operations, GDFs, and petroleum dry cleaning facilities. In the alternative, we also proposed permits by rule for use in Indian country for new or modified minor sources for three of the five source categories: Auto body repair and miscellaneous surface coating operations, GDFs, and petroleum dry cleaning facilities. Overall, we sought comment on all aspects of the permit documents and implementation tools for these five source categories. Specifically, Section VI. Summary of Specific Terms and Conditions of the General Permits and Request for Comment of the January 14, 2014, proposal, provided a summary of the specific terms and conditions of the general permits and indicated specific areas where we requested comment. Detailed responses to the comments on the permits and related tools and documents are addressed in Sections 3.1 to 3.5 of the RTC Document.[19]

2. Final Action, Comments and Responses

This section provides a brief summary of what the EPA considers to be the most significant comments received and our responses to those comments. Overall, on our January 14, 2014, proposal, we received 26 comments: 13 from industry (or their representatives), 11 from tribes (or their representatives), 1 from a local air quality agency and 1 from a state environmental agency.

Overall, based in part on our review of the comments, in this final action the EPA is issuing general permits for two source categories: HMA plants and SQCS facilities. These are available at: *http://www.epa.gov/air/tribal/tribalnsr.html.* We are also promulgating permits by rule for three source categories: Auto body repair and miscellaneous surface coating operations, GDFs, and petroleum dry cleaning facilities. These are available in this **Federal Register** notice and will be codified at 40 CFR 49.162. For all of these permits, the implementation tools and documents are available at: *http://www.epa.gov/air/tribal/tribalnsr.html.* The tools and documents are: Request for Coverage Forms (applications for general permits); Notification of Coverage Forms (permits by rule); Questionnaires; Instructions; PTE Calculators and Background Documents.

The following sections provide an abbreviated summary of significant comments on the proposed draft permits for the five source categories addressed in this final rule and our responses. In our final action, based in part on our review of the comments, we have made changes to the terms and conditions for the two draft general permits and the three proposed permits by rule and to the related implementation tools in the following areas: Setback requirements; throughput limits; various control requirements; and enhancements and clarifications to the implementation tools.

(a) Overview of Changes to Implementation Tools and Permits

In response to public comments, we are making the following changes to the implementation tools:

(1) Retitled the implementation tools for the three categories for which we are promulgating permits by rule to reflect that they are not general permits but are, in fact, permits by rule;

(2) For the Notification of Coverage Forms for the three permits by rule we are promulgating today, we have added requirements for (a) a list of equipment that will be present at the new or modified source; (b) PTE; (c) at existing sources, estimated annual emissions based on actual operating conditions and equipment [20] to satisfy the minor source registration requirement of § 49.160; and (d) clarified that sources covered by the permits by rule must also register under § 49.160 and that submittal of the Notification of Coverage Form satisfies that requirement;

(3) For the permits by rule, we have separated the screening processes from the Notification of Coverage Forms and created a separate document, ''Procedures to Address Threatened and Endangered Species and Historic Properties for New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule'';

(4) For the Request for Coverage Forms for the two general permits we are promulgating today, we have added a request for estimates of PTE and, at existing sources, actual emissions to satisfy the minor source registration requirement of § 49.160; clarified that sources covered by the general permits rule must also register under § 49.160 (submittal of the Request for Coverage Form satisfies that requirement); and added a section in which a source can list multiple source locations in which a portable source is planning to locate and for which it wants reviewing authority approval;

(5) For the instructions and questionnaires, we have made the changes necessary to reflect the changes made to the Notification of Coverage Forms and Request for Coverage Forms;

(6) For the questionnaires, to avoid confusion and redundancy with the eligibility criteria provided in the Notification of Coverage Forms and Request for Coverage Forms, we have removed the list of eligibility criteria at the front of the documents; and

(7) For the background documents, we have made the changes necessary to reflect the changes made to permit requirements in areas such as setbacks and throughput limits (see Sections IV.F. and IV.G. below for more detail).

In addition, we have made some changes in the permits being finalized in this action as a result of comments received on the July 17, 2014, proposed rule we issued for general permits and permits by rule in Indian country.[21] These changes concern general provisions in the permits and, thus, need to be reflected in all of the final permits from both proposals. One commenter stated that the condition in the draft general permits concerning Notification of Change in Ownership is unclear in establishing whether it is the responsibility of the new permittee or the old permittee to comply with the notification requirements. The same commenter requested that certain conditions of the draft general permit be clarified to cover situations in which there is a change of operator, but the ownership of the equipment is the same. In response to the comments, the EPA has clarified in the permits for the five source categories covered by this action that it is the responsibility of the *new*

[18] ''Managing Emissions from Oil and Natural Gas Production Indian Country,'' 79 FR 32502, June 5, 2014, *http://www.gpo.gov/fdsys/pkg/FR-2014-06-05/pdf/2014-12951.pdf.*

[19] The document is available online at: *http://www.epa.gov/air/tribal/tribalnsr.html* and at: Docket ID No. EPA–HQ–OAR–2011–0151.

[20] Estimates of emissions take into account equipment, operating conditions, and air pollution control measures and are calculated using the actual operating hours, production rates, in-place control equipment, and types of materials processed, stored, or combusted during the preceding calendar year.

[21] ''General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country,'' 79 FR 41846, July 17, 2014, *http://www.gpo.gov/fdsys/pkg/FR-2014-07-17/pdf/2014-16814.pdf.*

permittee to submit a written or electronic notice to the reviewing authority within 90 days before or after the change in ownership is effective. For the permits, we have also modified two Change in Ownership conditions [22] that appear in §§ 49.162(d)(5)(ii), 49.163(d)(5)(ii), and 49.164(d)(5)(ii) to include the word ''operator'' to clarify that these conditions also cover a change in operators where ownership of the equipment is the same.

One commenter stated that the term ''Responsible Official'' should be defined to ensure truth, accuracy and completeness of required reports. In response to the comment, EPA has added a definition of *Responsible Official* to each of the final permits.

Two commenters supported the proposed rule's approach of requiring each source to post the current approval of the Request for Coverage and to label each affected emissions unit and associated air pollution control technology with the identification numbers listed in the approval. One commenter recommended that the General Permit and the most current approval of the Request for Coverage for the permitted source ''must be made available immediately upon request,'' as opposed to ''must be posted.'' The commenter stated that it was not necessary to label the air pollution control equipment as the description and serial numbers are provided in the application. The EPA acknowledges the support of the commenters with respect to posting the Approval of the Request for Coverage. Upon review of comments received related to the posting of the General Permit in addition to the Approval of the Request for Coverage, EPA is revising the permits to exclude the requirement that the General Permit must be posted. Posting of the Approval of the Request for Coverage is required under 40 CFR 49.156(e)(6), but the General Permit itself is not required under the regulation to be posted and only needs to be available on site as needed. Regarding the labeling of emission units and air pollution control equipment, identification and labeling of these units is needed to facilitate identification of equipment covered under the General Permit by any potential inspectors. Therefore, EPA is finalizing the labeling requirements as proposed.

(b) Hot Mix Asphalt Plants and Stone, Quarrying, Crushing, and Screening Facilities

The EPA received numerous comments [23] on the draft General Air Quality Permit for New or Modified True Minor Source Hot Mix Asphalt Facilities in Indian Country and the related implementation tools.

One commenter recommended that the EPA use South Coast Air Quality Management District (SCAQMD) documents to develop some of the standards for asphalt plant equipment. We did consider SCAQMD rules when we developed some of the nonattainment area emission requirements in the HMA general permit because many of the nation's tribal nonattainment areas are in California. One commenter recommended that asphalt batch plants, process heaters, and storage tanks also be subject to Best Available Control Technology (BACT [24]). We agree that additional requirements for combustion units and asphalts tanks at HMA plants planning to locate or modify in nonattainment areas is appropriate and, accordingly, have modified the HMA general permit to include additional requirements for combustion units and asphalt tanks for nonattainment areas.

One commenter recommended that the EPA add a requirement for hot asphalt conveying, mixing, and truck load out to have ''Blue Smoke Control.'' The EPA considers the proposed opacity limits and weekly opacity monitoring requirements to be adequate for controlling visible emissions from HMA facilities. Two commenters stated that the requirements to submit annual compliance and deviation reports are overly cumbersome when compared to state requirements applicable immediately outside reservations. The EPA notes that the provision requiring submittal of annual compliance monitoring and deviation reports is included in the Federal Indian Country Minor NSR rule itself and is, therefore, properly included in general permits.

Commenters noted that, while the EPA used existing state general permits as the standard for the proposed HMA general permit, it picked more stringent permit requirements from the state permits reviewed, and created overly burdensome and duplicative requirements, creating an economic disadvantage for operators on tribal lands. The EPA notes that the primary purpose of a preconstruction review program is to protect air quality. The EPA believes that establishing a reasonable level of equality between what is required of sources locating in Indian country and sources locating outside of Indian country is an important secondary consideration; however, it is challenging to develop a single general permit for use across all tribal lands that would adequately protect air quality and create a perfectly level playing field.

Two commenters stated that the EPA failed to recognize that many HMA plants are portable in operation, and that the proposed general permit does not allow the flexibility necessary to easily relocate HMA plants. The EPA notes that the proposed HMA general permit includes provisions allowing relocation of the HMA facility as long as the alternate location(s) is (are) identified in the Approval of the Request for Coverage. For HMA facilities (and SQCS facilities), three commenters recommended that the EPA adopt an approach based on generalized relocation criteria that would not require identification of specific locations. The EPA disagrees with the commenters. The purpose of the preconstruction permitting program is to protect air quality and a determination of whether that goal is actually being met is dependent on knowing where a particular facility is going to be located. The EPA has, however, revised the Request for Coverage Form to clarify that the applicant may identify multiple locations for which the applicant is seeking coverage under the General Permit, including potential future locations.

One commenter stated that requiring operators to submit to the EPA a notice of construction each time the facility begins or resumes operations provides unnecessary enforcement risk to operators on tribal lands and should be stricken from the proposed HMA general permit. The EPA considers these notifications necessary to document when the requirements in the permit become applicable. Two commenters recommended that the EPA recognize an existing stack test on the same facility approved by an adjoining state agency, as stack tests are expensive, and the HMA industry has thin (profit) margins, creating an economic disadvantage for operators on tribal lands. The EPA has determined that it will allow a previous performance test that meets the performance test requirements

[22] The Change in Ownership condition in Section 6 of the proposed permits by rule has been dropped from the final permits by rule because there is no Approval of Coverage to change for permits by rule.

[23] Comments received on throughput limits and setback requirements for the HMA plants and SQCS facilities general permits are addressed in Sections IV.F. and IV.G., respectively.

[24] For federal purposes, BACT is a requirement for major sources under the PSD Program. However, the term is being used as it is used by the SCAQMD air program in the context of minor source NSR permitting in nonattainment areas.

identified in the HMA general permit to be used in lieu of an initial performance test, as long as conditions that might affect the facility's performance have not changed since the previous performance test was conducted.

One commenter stated that the restriction on HMA plants locating in severe and extreme ozone nonattainment areas and serious carbon monoxide (CO) nonattainment areas would place a restraint on any Indian tribe in these areas that might want to establish or attract an HMA plant for economic development purposes. The EPA notes that in severe and extreme ozone nonattainment areas, the air quality is already considerably degraded and that any additional impacts associated with a new facility must, therefore, be carefully evaluated before allowing construction to proceed. Although the EPA considered throughput limits for facilities locating in severe and extreme ozone nonattainment areas, we determined that these limits would need to be set at very low levels and would not provide sufficient flexibility for sources. The EPA revised the proposed HMA general permit to allow sources locating in serious CO nonattainment areas to be eligible for the permit, but maintained the exclusion for severe and extreme ozone nonattainment areas.

Two commenters noted that the proposed HMA permit requirements create major-source like requirements for true minor sources and synthetic minor sources, and noted that the proposed HMA general permit is a very complex permit for a not very complex industry. The EPA believes that the conditions in the general permit for this source category are appropriate. The complexity of this source category is demonstrated by there being multiple pieces of equipment and/or processes and pollutants and it being typically collocated with SQCS facilities. Protecting air quality for sources in such a source category necessitates a more comprehensive and specific set of emissions limitations and standards and associated requirements. It is important to also keep in mind that a comparison of the requirements in the EPA's proposed HMA general permit and the limits listed in Attachment A of the HMA background document [25] demonstrate that the EPA's proposed general permit for HMA plants is not the most stringent, nor the least stringent, in the country for HMA plants. The EPA's limits on throughput, fuel use, fuel sulfur content, nitrogen oxides emissions, CO emissions, and particulate matter (PM) emissions for attainment, unclassifiable or attainment/unclassifiable areas are all within the range of limits established by states in their general permits.

Two commenters noted that the EPA did not provide any opportunity to use on-specification waste oil or used oil, which is common in the asphalt industry, and could create an economic disadvantage for operators on tribal lands. Another commenter stated that the HMA permit sulfur content limit for liquid fuels (<0.0015 percent sulfur) is a very stringent on-road fuel standard being applied to stationary or non-road equipment, and that this creates a disadvantage for operations on tribal land. The EPA has accounted for the use of waste oil and recycled oil in the definition of ''distillate fuel'' in Attachment B to the final General Permit.[26] ''Distillate fuel'' is defined as ''fuel oils, including recycled oils that comply with the specifications for fuel oil numbers 1 and 2, as defined by ASTM 396, or equivalent.'' Regarding sulfur content limits, we have limited the sulfur content for all fuels used to less than 0.0015 percent sulfur in order to maintain consistency with the current fuel standards for sulfur in 40 CFR 80.510, which are already required for engines under NSPS subpart IIII (Stationary Compression Ignition Internal Combustion Engines) and National Emission Standards for Hazardous Air Pollutants (NESHAP) subpart ZZZZ (Stationary Reciprocating Internal Combustion Engines). One commenter noted that the EPA created duplicative requirements for engines that already have extensive federal requirements applicable through EPA engine standards: NSPS, Maximum Achievable Control Technology (MACT), and on-road engine rules. The EPA acknowledges that the permit includes requirements for engines that are covered by NSPS and NESHAP engine rules. However, we did not simply duplicate the NSPS and NESHAP requirements in the permits. Instead, we conducted a case-by case control technology review of the source category and established engine requirements that are consistent with the NSPS and NESHAP requirements. This approach is consistent with the requirement of the Federal Indian Country Minor NSR rule, which requires that each permit include applicable emission limitations that assure each affected emissions unit will comply with all requirements of parts 60, 61 and 63.

One commenter stated that fuel consumption limits are overly burdensome and unnecessary for determining compliance with the HMA general permit, and recommended that they be removed from the General Permit. The EPA is retaining the fuel consumption limits in the final general permit in lieu of ton-per-year emission limits because tracking fuel use is easier for sources and, thus, reduces the burden of having to calculate and track emissions. Two commenters noted that the EPA did not provide any allowance or justification for not allowing wet scrubbers for particulate controls when they may be allowed on adjoining state lands, creating an economic disadvantage for operators on tribal lands. The EPA agrees with the commenter and has added provisions to the HMA general permit to allow for the use of a wet scrubber in appropriate circumstances. One commenter recommended that the EPA remove the provision requiring that extra bags and spare parts be maintained onsite, and allow operators the choice to shut down a facility that has a torn bag in the baghouse until a replacement is transported to the site. The EPA agrees with the commenter and has modified the permit to suggest the permittee maintain extra bags and spare parts on site to ensure timely repair. However, replacements bags can be transported on site when needed. In either case, the permittee must shut down the facility until a replacement bag is installed.

The EPA received numerous comments on the draft General Permit for New or Modified True Minor Source Stone Quarrying, Crushing and Screening Facilities in Indian Country and the related implementation tools. Two commenters stated that a monthly total emissions limitation based on a 30-day rolling total would be appropriate since an SQCS facility can relocate much like an HMA plant, and even perhaps to an area in nonattainment for $PM_{10}$. One commenter recommended that, as an alternative, the EPA could retain the 12-month period limits on raw material throughput but establish different throughput production limits for areas in attainment and for areas in serious, severe, or extreme nonattainment for PM.[27] The EPA has considered the commenters' suggestion

[25] The background documents are available online at: *http://www.epa.gov/air/tribal/tribalnsr.html* and at Docket ID No. EPA–HQ–OAR–2011–0151.

[26] The final general permits are available online at: *http://www.epa.gov/air/tribal/tribalnsr.html* and at Docket ID No. EPA–HQ–OAR–2011–0151.

[27] Subpart 4, which contains the provisions governing requirements for PM nonattainment areas, provides for only moderate and serious classifications.

and agrees that the approach used in the HMA general permit is appropriate for SQCS facilities since they often also need to relocate and are frequently collocated with HMA plants. The EPA replaced the proposed annual throughput limit with monthly throughput limits for both raw material and fuel. The limits are set at a level which will generally keep the combined emissions of a collocated SQCS facility and a HMA plant at a level that does not trigger title V applicability (see Section IV.K. Use of More Than One General Permit and/or Permit by Rule for a Source at a Single Location). The general permits for both HMA plants and SQCS facilities are written for use by both true minor sources and synthetic minor sources. The permits contain one set of requirements for each that apply to true minor sources and synthetic minor sources and include a margin of safety between the permitted throughput limit and the major source thresholds (see Section IV.I. Use of General Permits and Permits by Rule to Create Synthetic Minor Sources). In addition, the control technology determinations proposed are contained in the final general permits. They cover a myriad of emissions points at sources in these categories, including engines, mixers, dryers, and heaters.

One commenter recommended that the EPA consider SCAQMD Rule 1157 to address particulate emissions from SQCS equipment. The EPA has reviewed Rule 1157 and notes that the draft permit conditions appear to be at least as stringent as those suggested by the commenter. One commenter noted that the draft general permit assumes that all engines used for this operation would be diesel-fired compression ignition engines and asked why provisions for spark ignition (SI) engines and the use of other fuels were not included. The EPA has not included provisions for SI engines in the final SQCS permit because the EPA believes that it is unlikely that many minor sources in this source category are using SI engines. Electricity for the motors running the crushers, screens, and conveyors at SQCS facilities is provided either by grid electric power or by diesel engines. Diesel engines are preferred in this source category because of their improved efficiency and reliability in these heavy work-intensive, industrial applications versus SI engines. In the EPA's view, adding SI engines to the SQCS general permit is, therefore, not necessary.

One commenter recommended that the general permit reference the specifics of compliance such as stack testing and emission limits to the NSPS and MACT requirements in the federal regulations. The EPA notes that the emission limitations in the SQCS general permit are intended to ensure compliance with the applicable NSPS and NESHAPs for this source category, as required by the Federal Indian Country Minor NSR rule. However, the EPA's pre-construction permitting program under the Federal Indian Country Minor NSR rule is not an operating permit program. The terms and conditions in permits issued pursuant to the Federal Indian Country Minor NSR rule are enforceable independent of the NSPS and NESHAP requirements.

Two commenters stated that the requirements in the SQCS permit can be damaging to tribal member-owned companies and may cause them to go out of business. The EPA does not believe that the requirements in the SQCS permit will be damaging to tribal member-owned companies. During the development of the draft permit, the EPA conducted research to identify, review and incorporate similar throughput limits, fuel usage limits, fuel sulfur limits, fugitive dust suppression methods, and engine emission and opacity limitations in state-issued permits. Based on this analysis, we have determined that the emission limitations and controls proposed in the general permit for both attainment and nonattainment areas are consistent with what is required of similarly located SQCS facilities across the country and, therefore, would not present an unfair or undue burden for tribal member-owned sources.

The EPA received comments on whether to establish a single, combined permit for HMA and SQCS facilities. One commenter stated its preference for a permitting approach that requires each HMA plant and SQCS facility to request coverage under its own general permit, rather than placing both sources under one general permit. Another commenter stated that collocation of HMAs and SQCSs is quite probable, but believed that they cannot be combined and permitted in one permit. One commenter did not support offering a single permit for both facilities because most often it would be two different companies. One commenter recommended that HMAs and SQCSs be permitted separately, but when operated at the same location and utilizing materials from one operation to another that they combine (and limit) the emissions (as if they were one source) to protect the airshed without creating an emissions loophole. Another commenter recommended that a single general permit should be issued covering sources that are co-located in addition to issuing separate general permits for each source, noting that the requirement for co-located sources would be used to ensure that the two sources' combined emissions are below the major source thresholds.

The EPA has considered the concerns and recommendations of commenters and has determined that it is appropriate to maintain separate permits for HMA and SQCS sources even when they are co-located. In the final HMA and SQCS general permits, however, the EPA is providing alternative throughput and fuel limits for instances where an HMA operation and an SQCS operation are co-located and the owner/operator wants to ensure that combined emissions are below the title V permitting thresholds. Each source should contact its reviewing authority if it intends to rely on the emission limitations and standards in the HMA and SQCS general permits to prevent having to obtain a title V permit. The Request for Coverage Forms were revised to allow applicants to request the co-location option.

In addition, the co-location option for these source categories is not available in serious, severe and extreme ozone nonattainment areas. For severe and extreme areas, the co-location option is not available because the HMA general permit alone is not available in those areas because the major stationary source thresholds are very low in these types of areas, and we do not envision that any minor source HMA plants would be able to meet the thresholds through a general permit. Similarly, for serious areas, in trying to set co-location limits for these source categories that are set low enough to meet the 50 tons per year major source threshold for serious areas, we found that we would have to set the throughput limits at levels so low that we do not envision minor, co-located sources being able to meet the limits. In these cases, we believe that co-location is more appropriately handled for these sources thorough a site-specific permit.

(c) Auto Body Repair and Miscellaneous Surface Coating Operations

The EPA received numerous comments on the draft General Air Quality Permit for New or Modified True Minor Source Auto body Repair and Miscellaneous Surface Coating Operations in Indian Country [28] (the

[28] The comments we received also apply to the Air Quality Permit by Rule for New or Modified True Minor Source Auto body Repair and Miscellaneous Surface Coating Operations in Indian Country that the EPA proposed in the alternative.

Continued

Auto body General Permit) and the related implementation tools. One commenter recommended that, for ozone nonattainment regions, the EPA should consider requiring the most stringent emissions limitation or installation of BACT based on the requirements of the neighboring air district regardless of a facility's PTE or throughput, and recommended that the EPA use the most recent version of the SCAQMD BACT requirements for serious, severe, and extreme ozone nonattainment regions. The EPA has incorporated many of the SCAQMD BACT [29] requirements, as well as amended volatile organic compound (VOC) content limits, into the Permit by Rule that we are finalizing for this source category versus a general permit. We did not include requirements for activities that we do not expect to be located at sources eligible for this permit by rule.

One commenter stated that the materials-use provisions in the draft Auto body General Permit are unclear, while another commenter recommended that the EPA specify the coating VOC content limits in grams per liter or pounds (lbs) per gallon, excluding water. The EPA based the material-use provisions in the draft Auto body General Permit on a worst-case VOC content limit of 8.34 lbs per gallon and then limited use to 5,000 gallons of materials with a VOC content of 8.34 lbs per gallon or less per year. As recommended, the EPA has also specified coating content limits in grams per liter. One commenter recommended that an emission limit based on the Federal Indian Country Minor NSR rule ton per year permitting thresholds be used instead of a throughput limitation. The EPA chose to include limitations on material use in lieu of ton-per-year emission limits because tracking material use is easier for sources and, thus, reduces burden. The EPA's research of state permitting programs indicates that states are using material-use limits for these sources.

One commenter recommended that the EPA consider adding a requirement that prohibits the use of automotive coatings that contain cadmium or chromium to help ensure adequate public health protection. The Federal Indian Country Minor NSR rule permitting program does not provide the EPA authority to regulate hazardous air pollutants (HAPs) other than through the issuance of a synthetic minor permit. Therefore, the content limits do not address cadmium or chromium. One commenter recommended that the EPA add limits and work practices for stripping operations in the permit. The EPA notes that the recommended limits for stripping operations primarily address HAPs. As the EPA lacks authority under the NSR program to impose such limits and the commenter did not provide information indicating that such work practices are necessary for other reasons, the EPA has not included limits or work practices for stripping operations.

One commenter stated that the term ''reasonable time'' is subjective and not easily enforceable as it pertains to reviewing authority information requests of permittees. This commenter recommended that a specific time frame should be included in the permit. The EPA agrees with the commenter and replaced ''reasonable time'' with ''30 days unless another timeframe is specified by the EPA.'' We have made this change in all of the final permits in this action. One commenter recommended that the Auto body General Permit identify a specific test method to ensure consistency in determining the efficiency of filters used in conjunction with capturing paint overspray in enclosed painting areas. The EPA agrees and has revised the permit by rule accordingly. One commenter noted that airless and air-assisted airless spray guns are not equivalent to high volume, low pressure (HVLP) spray guns and recommends that their use not be allowed under Section 2: Emission Limitations and Standards, Conditions 19 and 33 of the draft general permits, unless the spray gun manufacturer can demonstrate that their device is capable of achieving transfer efficiency comparable to that of an HVLP spray gun. The EPA agrees with the comment in the context of serious, severe, and extreme ozone nonattainment areas. The more stringent requirement recommended by the commenter will only apply to these nonattainment areas. For other areas, consistency with the spray gun requirements in 40 CFR part 63 Subpart HHHHHH is more appropriate. One commenter requested that the exemption for spray guns with a cup capacity of 3 fluid ounces or less be removed for facilities located in serious, severe or extreme ozone nonattainment areas. The commenter recommended continuing to exempt spray guns with this capacity used in air brush operations. The EPA agrees, and has changed the permit by rule. One commenter recommended that the EPA require installation and maintenance of a pressure gauge across each filter bank. The EPA agrees, and has revised the permit by rule, accordingly.

One commenter recommended that the EPA revise the definitions for ''Air Brush Operations,'' ''Freeboard Area,'' ''Freeboard Height'' and ''Liquid Leak.'' The EPA agrees that the suggested changes are appropriate and, therefore, revised the definitions as suggested, except for ''Air Brush Operations'' because the term is not included in any of the conditions of the final Auto body Permit by Rule. One commenter recommended that, in the surface coating permit, the expected transfer efficiency of the HVLP spray gun be defined. The EPA disagrees. The draft Auto body General Permit defines an HVLP spray gun consistent with 40 CFR part 63 Subpart HHHHHH, and we prefer to maintain consistency with this regulation. One commenter stated that the materials use provisions for cold cleaning solvent in the draft Auto body General Permit are unclear, and recommended that an emission limit be used instead. The EPA believes that the requirements are sufficiently clear and that the materials use requirements are preferable to an emission limit in this context because it is far easier for small sources to track material use than emissions. As a result, the EPA is retaining material use limits in the final permit by rule.

One commenter requested clarification on whether sources that do not exceed the permitting limit in the Federal Indian Country Minor NSR rule, but are subject to the MACT, still need to obtain a general permit. In response, the EPA notes that sources that are subject to a NESHAP, but whose emissions do not exceed the permitting thresholds for the Federal Indian Country Minor NSR rule, are not required to obtain a minor source permit. One commenter stated that the Auto body General Permit requires the permittee to keep records of the VOC and HAP content of the solvent used in a solvent degreaser, but asked why the permittee would need to keep records when there are no limits on the VOC content of the solvents. The EPA agrees and revised these recordkeeping requirements to require the Material Safety Data Sheet (MSDS) to be maintained for each solvent degreaser, consistent with the requirements for other VOC-containing material in the permit.

One commenter noted that, in the notification of construction or modification requirement, it is not clear

In this final action, we are promulgating a permit by rule for the auto body source category.

[29] For federal purposes BACT is a requirement for major sources under the PSD Program. However, the term is being used as it is used by the SCAQMD air program in the context of minor source NSR permitting in nonattainment areas.

whether the notification required for beginning operations is within 30 days of start of construction or within 30 days after operations begin or resume. The EPA has revised the final Auto body Permit by Rule to clarify that the permittee must provide written notice within 30 days of beginning construction, and within 30 days of beginning initial operations or resuming operations after a modification.

One commenter requested clarification on when the refresher training is required for spray booth operators. The EPA has updated § 49.162(f) to the final Auto body Permit by Rule to specify that training must be conducted within 180 days for new hires and that operators must be re-certified at least every 5 years thereafter.

(d) Gasoline Dispensing Facilities

The EPA received numerous comments on the draft General Air Quality Permit for New or Modified True Minor Source Gasoline Dispensing Facilities in Indian Country [30] (the GDF General Permit) and the related implementation tools.[31] One commenter stated that, for GDFs, the percent onboard refueling vapor recovery (%ORVR) estimate seems optimistic, and that basing applicability on throughput based on those assumptions may under estimate source emissions. The EPA disagrees with the commenter. The EPA determined the %ORVR for the vehicle fleet based on an agency analysis using the 2012 memorandum, ''Updated Data for ORVR Widespread Use Assessment,'' [32] and believes this analysis is well substantiated. Therefore, the EPA has continued to rely on this analysis in establishing the throughput limits in the Permit by Rule that we are finalizing for this source category versus a general permit. One commenter supports the inclusion in the GDF General Permit of standing loss control (SLC) requirements for above ground storage tanks (ASTs) in those parts of Indian country that are located in serious, severe and extreme ozone nonattainment areas. The EPA has determined that SLC requirements for VOC emissions from ASTs should be applied to GDFs in Indian country serious, severe and extreme ozone nonattainment areas as we proposed. In doing this, the EPA has tried to balance the requirement to protect the National Ambient Air Quality Standards (NAAQS) with the desire to provide a level regulatory playing field.

One commenter noted that the proposed GDF General Permit requires Stage I control for both underground and aboveground storage tanks and SLC for aboveground storage tanks, but that Stage II control is not required under the General Permit, even though Stage II control is still required in some states. The commenter recommended that the EPA require Stage II controls in states that still require Stage II controls, Phase II Enhanced Vapor Recovery (EVR) systems, and Phase II EVR systems in all serious, severe or extreme nonattainment areas. Another commenter recommended that the EPA require In-Station Diagnostics (ISD) for all GDFs that dispense more than 600,000 gallons per year. Another commenter recommended that vapor recovery systems be certified.

The EPA previously issued a notice of final rulemaking to allow states to phase out Stage II controls for serious, severe and extreme ozone nonattainment areas (77 FR 28772, May 12, 2012). At that time, the Administrator made the determination that ORVR is in widespread use, and that Stage II controls could be removed to reduce costs for redundant control, as authorized under section 202(a)(6) of the CAA. The rule allowed, but did not require, states to discontinue Stage II vapor recovery programs. California has chosen to continue requiring the program. The additional emission reductions associated with the use of Stage II controls continue to be necessary and are required to be included in California plans for demonstrating how they will attain the NAAQS. We do not, however, anticipate any other areas in the country continuing to require Stage II controls at new or modified GDFs. Based on California's decision to continue to require the use of Stage II controls, and the fact that such controls are not necessary in other areas of the country, we have, however, determined that the use of the proposed permit by rule, which does not include Stage II controls, in California is not appropriate. As a result, while the final permit by rule for GDFs will not include Stage II controls, sources located in California will not be eligible to use the permit by rule. This approach will allow EPA Region 9, the current reviewing authority in all areas of California, to develop a general permit or permit by rule for areas within California that is tailored to address the unique air quality concerns in that area of the country. Requirements for the use of ISD and the certification of vapor recovery systems are not included in this final permit as these requirements are associated with Stage II systems.

One commenter supports the exemption for tanks with less than 250 gallon capacity. Commenters requested that the EPA modify several conditions in the draft GDF General Permit and Appendices to clarify control equipment requirements, add housekeeping measures, revise testing requirements, delete inconsistencies, and revise definitions. The EPA agrees with some of these requests and disagrees with others. The EPA made changes to the permit where we deemed that the change would strengthen the permit's ability to protect air quality. One commenter requested that the EPA revise the monitoring requirements in the draft GDF General Permit to add a requirement for the daily visual inspection of equipment. The EPA revised the permit to include a requirement for a daily visual inspection of equipment in extreme ozone nonattainment areas. One commenter recommended that the EPA make several changes in the draft general permit to Attachment C: Vapor Balance System Design Criteria, Management Practices, and Performance Testing, Paragraph 11, relating to applicability, technical references, and certifications for ASTs. The EPA concurs and has made the changes.

One commenter recommended that the MACT standard for GDFs, 40 CFR part 63, subpart CCCCCC, should be referenced in the GDF General Permit, and noted that the permit conditions in the draft general permit are more stringent than are the MACT requirements in some respects. The requirements included in the permit are intended to harmonize with the existing NESHAP rule to the greatest extent possible. We have tried to maintain consistency with 40 CFR part 63, subpart CCCCCC to streamline the permit and to reduce burden to sources who may need to comply with both requirements. More stringent requirements were included for GDFs in certain nonattainment areas to protect the NAAQS.

(d) Petroleum Dry Cleaning Facilities

The EPA received comments on the draft General Air Quality Permit for New or Modified True Minor Source Petroleum Dry Cleaning Facilities in

[30] The comments we received also apply to the Air Quality Permit by Rule for New or Modified True Minor Source Gasoline Dispensing Facilities in Indian Country that the EPA proposed in the alternative. In this final action, we are promulgating a permit by rule for the GDF source category.

[31] While we did not receive comments on setting a throughput limit for the GDF permit by rule for marginal and moderate ozone nonattainment areas, we are adding one for the GDF permit by rule for those areas (see Section IV.F. for a fuller discussion of throughput limits).

[32] The memorandum can be found at: Docket Id. No. The EPA–HQ–OAR–2010–1076.

Indian Country [33] (the Petroleum Dry Cleaning General Permit) and the related implementation tools. Two commenters agreed with the throughput limits and inspection requirements for dry cleaning facilities, while another commenter stated the inspection timeframes and repair deadlines for dry cleaning dryers were burdensome. One commenter recommended that the EPA include BACT [34] guidelines for new petroleum dry cleaning equipment in nonattainment areas identical to the SCAQMD BACT guidelines, while another commenter noted there would be costs associated with meeting the draft requirements for nonattainment areas in the permit. One commenter recommended that the MACT standard for dry cleaners be referenced in the General Permit. One commenter stated its belief that the draft permit conditions are more stringent than the MACT requirements, and recommended that the EPA remove any sections from the General Permit that duplicate the MACT rule. The EPA has determined that it will maintain the proposed throughput limits and inspection requirements in the Permit by Rule that we are finalizing for this source category versus a general permit. The EPA believes the timeframe for inspections and repair is reasonable, as these are equivalent to requirements in the Petroleum Dry Cleaners NSPS (40 CFR part 60, subpart JJJ). The EPA intended to include more stringent requirements for sources locating in certain ozone nonattainment areas. The EPA did not intend to include standards from the NESHAP standard for perchloroethylene dry cleaners (40 CFR 63, subpart M) in the permit by rule as the permit is not intended to regulate emissions of HAP. Instead, the EPA drew upon requirements from the Petroleum Dry Cleaners NSPS (40 CFR part 60, subpart JJJ) in establishing the requirements in the draft permit. The EPA believes that more stringent provisions are necessary in serious, severe, and extreme ozone nonattainment areas and has included such provisions in the final permit by rule. As these nonattainment provisions are largely drawn from state and local requirements, the EPA believes that the final permit conditions are reasonable for areas with impaired air quality and consistent with the requirements in other areas outside of Indian country.

*B. Requirements of the Endangered Species Act (ESA) and the National Historic Preservation Act (NHPA)*

1. Proposed Rule

The ESA requires federal agencies to ensure, in consultation with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service (the Services), that any action they authorize, fund, or carry out will not likely jeopardize the continued existence of any listed threatened or endangered species, or destroy or adversely modify the designated critical habitat of such species. Under relevant ESA implementing regulations, federal agencies consult with the Service(s) on actions that may affect listed species or designated critical habitat.

The NHPA requires federal agencies to take into account the effects of their undertakings on historic properties—*i.e.,* properties that are either listed on, or eligible for listing on, the National Register of Historic Places—and to provide the Advisory Council on Historic Preservation (the Council) a reasonable opportunity to comment on such undertakings. Under relevant NHPA implementing regulations, NHPA consultations are generally conducted with the appropriate Tribal and/or State Historic Preservation Officers in the first instance, with opportunities for direct Council involvement in appropriate circumstances. The Federal Minor NSR Program in Indian Country has increased the number of activities for which the EPA is the permitting authority. To ensure appropriate consideration of listed species and historic properties, we provided draft screening processes in Appendices A and B to the draft Request for Coverage Forms for the draft general permits that we made available for comment.

2. Final Action, Comments and Responses

This section provides a brief summary of significant comments received and our responses. Overall, as a result of the comments in this final action, we are largely retaining the processes we proposed, but with some important adjustments. In terms of process, as discussed in Section IV.H. Permit by Rule Regulatory Framework, we have modified the permit by rule process to require that a source planning to seek coverage under a permit by rule must first demonstrate it has adequately completed the screening processes for threatened and endangered species and historic properties, and received a written letter from the EPA indicating that the processes have been satisfactorily addressed, prior to notifying the reviewing authority that it is covered under the permit by rule.[35] (To this end, as noted above, for the permits by rule, we have separated the screening processes from the Notification of Coverage Forms and created a separate document, ''Procedures to Address Threatened and Endangered Species and Historic Properties for New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule.'') Responses to individual comments are set forth in Section 2.4 of the RTC Document.

One commenter expressed support for requiring applicants to meet the screening requirements for protected resources. We note that the EPA has revised terminology in the screening procedures for the protected resource screening procedures to provide greater clarity, but has otherwise largely retained the proposed procedures. One commenter asked if the EPA will be including the endangered species and historic preservation requirements in all air permitting actions. At this time, the EPA is only requiring sources to complete threatened and endangered species and historic property screening procedures in order to obtain coverage under the general permits and permits by rule being finalized in this action. Any issues related to other air permitting action not included by this final action are beyond the scope of this action.

One commenter inquired if the threatened and endangered species clause (*i.e.,* the ESA) is also included in the title V permits. This rulemaking action is not within the scope of the title V permit program (*i.e.,* sources in Indian country that are defined as major sources or otherwise required to obtain operating permits under 40 CFR part 71); thus, the comment is outside the scope of this action. One commenter requested clarification on which geographic areas the ESA ''action areas'' would encompass. For purposes of the listed species screening procedures, the EPA uses the definition of the term ''action area'' found in 50 CFR 402.02 of the ESA regulations; however, we have added additional information in the

[33] The comments we received also apply to the Air Quality Permit by Rule for New or Modified True Minor Source Dry Cleaning Facilities in Indian Country that the EPA proposed in the alternative. In this final action, we are promulgating a permit by rule for the petroleum dry cleaning source category.

[34] For federal purposes BACT is a requirement for major sources under the PSD Program. However, the term is being used as it is used by the SCAQMD air program in the context of minor source NSR permitting in nonattainment areas.

[35] In some cases, the EPA may delegate to an Indian tribe the authority to assist the EPA with administration of the Federal Indian Country Minor NSR rule (including the permits by rule). However, even where such a delegation occurs, the EPA will retain responsibility for providing notification to sources that the listed species and historic property processes have been satisfactorily addressed.

screening process to further explain considerations in determining the action area.

Multiple commenters expressed concerns about the ability of permit applicants to meet the time, expertise, and cost burdens associated with complying with the listed species and historic property screening requirements. The EPA understands that satisfactorily addressing the screening procedures for threatened and endangered species and historic properties will impose some burden on sources seeking permits. However, we have attempted to streamline the screening processes in order to minimize the effort needed to complete them. For example, both sets of procedures have been clarified to make more explicit that sources can rely on prior assessments performed by other federal agencies to satisfy the procedures.

One commenter believes that it is not appropriate for the EPA to use a process to demonstrate compliance with the ESA and NHPA that is modeled after the National Pollutant Discharge Elimination System (NPDES) general permit for Stormwater Discharge from Construction Activities. The commenter requested that the EPA defer the regulation of ESA and NHPA to Federal Land Management Agencies (FLMs). The EPA believes that the screening procedures included in the general permits and permits by rule are appropriate means to ensure proper review of possible effects on threatened and endangered species and historic properties as sources seek coverage under the permits. Where available, and to avoid duplication of efforts, we believe it is appropriate for facilities seeking to be covered under the general permits or permits by rule to use listed species and historic property assessments, analyses, and outcomes obtained through the FLMs' separate compliance with the ESA and NHPA in connection with their own actions to satisfy the relevant screening procedures of the minor NSR general permits and permits by rule. For the permits by rule, we have modified the protected resource procedures in Appendix A of the document titled ''Procedures to Address Threatened and Endangered Species and Historic Properties for New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule'' to clarify that this approach is the first consideration in the screening process. For the general permits, we have made the same change to the protected resource procedures that are attached to the Request for Coverage Forms.

One commenter stated that, because no regulatory text has been provided with respect to the EPA's proposed approach to addressing ESA and NHPA requirements, it is impossible to fully evaluate the EPA's proposal. The commenter also noted that the EPA's ESA/NHPA approach poses a number of potentially significant problems: (a) The proposed rule does not expressly address whether this rulemaking action is itself subject to the ESA and NHPA; (b) the process the EPA identifies for ensuring compliance with the ESA and NHPA involves requiring applicants to interface with the agencies responsible for guiding implementation of the ESA and NHPA in the absence of any procedure governing that interaction; (c) there are no clear timeframes for these agencies to respond to an applicant's request for coordination; and (d) the legal consequences of certifying compliance with the ESA and NHPA are undefined. This commenter also noted that the process does not acknowledge the importance of the EPA's role in compliance with the ESA and NHPA, stating that the no effect determination, or any obligation to undertake consultation with other federal agencies, is the EPA's responsibility and that the EPA should not defer to the opinions of other agencies.

The EPA notes that it is the issuance of the general permit or permit by rule that triggers any ESA/NHPA requirement, not the separate coverages of individual sources. To address these requirements, the EPA has established the listed species and historic properties screening procedures via this action to provide an effective means of identifying and addressing any impacts on the protected resources as sources seek coverage. We note that sources must demonstrate satisfactory completion of the screening procedures and that this demonstration must form part of the legal basis that the source is eligible for coverage under the general permit or permit by rule. To provide an opportunity for the public to review these screening procedures, all of the five proposed general permits and associated implementation tools were made available in the docket for review and comment. The applications for each draft general permit contain appendices (Appendix A for listed species and Appendix B for historic properties) with the detailed screening procedures that an applicant will follow to assess the potential impacts of their source as it pertains to the relevant protected resources. We specifically requested comment on these general permits and implementation tools and believe that our process provided an appropriate opportunity for public involvement.

One commenter recommended that the EPA should include a determination expressly finding that the minor sources on tribal lands subject to the Federal Indian Country Minor NSR rule will have no effect on any species listed under the ESA, nor any potential effects on resources protected by the NHPA in the final permit. This commenter stated that the use of the term ''significant risk'' (''. . . based on the evaluation of available information, that the sources that are the subject of this proposal are unlikely to present a significant risk to listed species and critical habitat and to historic properties . . .'') confuses the issue, as that term is not the relevant standard under the ESA or NHPA for determining whether regulatory requirements pursuant to those statutes apply. The commenter believes that the EPA should instead conclude that minor sources on tribal lands subject to the Federal Indian Country Minor NSR rule are likely to have ''no effect'' on any listed species or critical habitat, and no potential to affect historic properties.

The EPA does not believe that a single determination for all new sources in Indian country that may be covered under a general permit or permit by rule would be appropriate. To ensure that appropriate consideration of any potential impacts on listed species or historic properties occurs, we believe a level of site-specific assessment is needed, primarily for the purpose of investigating potential land disturbance activities but also to address any other potential impacts. We believe the source screening procedures contained in the Request for Coverage Forms for general permits and ''Procedures to Address Threatened and Endangered Species and Historic Properties for New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule'' for permits by rule are the most efficient way to make those determinations.

### *C. Use of Streamlined General Permit Applications*

#### 1. Proposed Rule

In the proposed rule, we sought comment on the appropriateness of utilizing permits by rule for three source categories as an alternative to general permits: auto body repair and miscellaneous surface coating operations, GDFs, and petroleum dry cleaning facilities. We specifically requested comment on the permit by rule notification procedures.

2. Final Action, Comments and Responses

This section provides a brief summary of significant comments received regarding the appropriateness of utilizing permits by rule and streamlined notification forms, and our responses. (Since we are not issuing general permits for the three source categories, we will not be issuing any general permit applications for those categories.) Responses to comments on the use of streamlined notification forms for the permits by rule in today's action can be found in Section 4.0 of the RTC Document.

Several commenters provided support for EPA's proposed use of streamlined permit applications for permits by rule. Some commenters noted that several states and local reviewing authorities use permits by rule to authorize construction of minor sources and that the EPA has approved several state or local permits by rule in State Implementation Plans. Three commenters asserted that the use of permits by rule would expedite the permitting process and reduce administrative burdens and costs for permitting agencies and/or operators. Four commenters opposed the use of permits by rule for the three source categories. One commenter also opposed the use of permits by rule for any future source categories that the EPA may propose. One of these commenters stated that a lack of notification could result in a permittee missing out on critical permitting steps. The commenter also asked how the EPA or a tribe would be able to review and confirm that a facility is providing the correct information. The commenter asserted that this scenario is no different than the process before the Federal Indian Country Minor NSR rule.

The EPA believes that the use of permits by rule is appropriate for the three source categories. Permits by rule provide a streamlined approach that (a) reduces the time permitting authorities must devote to reviewing permit applications and issuing permits, (b) protects air quality by controlling emissions-generating activities that pose little environmental concern and (c) simplifies the permitting process for sources that pose little environmental concern. The EPA has attempted to balance air quality concerns in Indian country with the resource and workload needs of reviewing authorities. The issuance of general permits for these facilities as compared to covering them with a permit by rule would greatly add to the workload of the reviewing authority without providing greater benefits to air quality. Given the relative simplicity and generally lower emissions of these sources, we have determined that we do not need to conduct a case-specific review to evaluate whether an individual source qualifies for the permit, and we are comfortable requiring only a streamlined notification form from these sources. Because we will need to continue to balance the workload and resource needs of the reviewing authority with the need to protect air quality, we do not agree with the comment that permits by rule should not be used for any future source categories. We note that the permit by rule notifications do not ask for detailed source information because these source categories reflect facilities that are straightforward in their configuration and emissions (they are primarily VOC emission sources), and do not require detailed review or confirmation of the information.

*D. Administrative Aspects of General Permits*

1. Proposed Rule

The EPA requested comment on the administrative aspects of general permits. Specifically, among other areas, we requested comment on two issues:

(a) Whether the EPA's proposed approach of incorporating by reference each reviewing authority's approval of a Request for Coverage into the general permit is necessary and appropriate; and

(b) The appropriateness of draft permit terms related to the reviewing authority's ability to reopen, revise, or terminate an individual approval of coverage under the general permit.

2. Final Action, Comments and Responses

This section provides a brief summary of significant comments received related to administrative procedures for permit issuance and obtaining coverage under a general permit and permit by rule. Responses to these comments are also addressed in Sections 1.2 and 1.3 of the RTC Document. In this final action, we are providing responses to issues raised in comments, but we have concluded that those comments do not necessitate any substantive changes to the administrative aspects of the permits.

One commenter disagreed with the EPA's proposed procedure for amending general permits, noting that the provision is overly broad and inconsistent with the procedures for amending source-specific permits. This commenter recommends that the EPA treat sources covered by general permits (or permits by rule) in the same manner as facilities covered by source-specific permits.

The EPA's procedure for issuing general permits is governed by 40 CFR 49.156, and the EPA interprets the Federal Indian Country Minor NSR rule to require the provision in 40 CFR 49.156 to be used anytime a general permit is revised (amended). In the proposal (79 FR 2546), the EPA clarified that although a general permit may be revised in the future, we do not intend to use the revision process to subject existing sources already covered by a general permit to new control requirements, unless and until they modify. This process is consistent with how site-specific permits are revised.

A few commenters expressed concern on how the Federal Indian Country Minor NSR rule would address permitting a source that could cause or contribute to a NAAQS violation or a PSD increment violation. Commenters also objected to the EPA's stated preference for general permits, noting that the proposed rule does not address the fundamental problem of a lack of staff at local agencies to process these new regulatory requirements, and recommended that the EPA include a staffing plan and the funding to support it, or use permits by rule instead. Commenters noted that the EPA's ability to terminate a permit for ''cause'' would create uncertainty, and puts tribally owned companies at risk. The EPA believes that the ability to deny coverage is necessary to prevent exceedances of the NAAQS due to cumulative increases in emissions. The EPA recommends that tribes planning to construct tribally-owned facilities work with the specific reviewing authority in their area to address these concerns. The general permit program will help alleviate any potential backlog in the issuance of minor source permits to sources that would otherwise require site-specific permits, allowing limited agency resources to be focused on more complicated sources that require more in-depth review. The conditions under which a permit can be terminated for cause are defined in each general permit; therefore, the situations for which coverage under a general permit would be terminated are fairly specific.

One commenter pointed out that the proposed rule did not include specific regulatory language for any of the proposed permits by rule. This commenter argued that the lack of regulatory text prevented full and complete public review and comment on the proposed rule. The commenter asked that the EPA provide regulatory text and a full explanation of the permit

by rule approach before finalizing the rule. The EPA did not provide specific regulatory language for any of the proposed permits by rule, but rather proposed to codify the requirements of the proposed general permits of the specified source category. For the permits by rule in this final action, we are codifying the requirements as contained in the draft general permit for the three source categories, including changes that we have identified are appropriate based on our review of public comments. We believe that the proposed general permits have provided the public with a sufficient understanding of the contents of the final rule, and, therefore, satisfy our obligations under section 301(a) of the CAA.

*E. Control Technology Review*

1. Proposed Rule

In the proposal, we requested comment on the EPA's conclusion, based on its control technology review, that the control measures in the draft general permits are currently used by other similar sources in other areas of the country and that the measures in the draft permits are, therefore, technically and economically feasible and cost-effective.

2. Final Action, Comments and Responses

This section provides a brief summary of significant comments received and our responses. Responses to these comments are also addressed in Section 2.2 of the RTC Document. The EPA is largely retaining the basic approach to the control technology review outlined in the January 14, 2014, proposal.

A few commenters expressed concern with the EPA's decision to apply local control requirements on a nationwide basis. They stated that this might lead to a competitive advantage or disadvantage for sources locating in Indian country and tribes could lose revenue as a result. Commenters recommended that the EPA issue regional permits, and that the control requirements for each region should be based on the rules and regulations in adjacent areas, and on the nonattainment status of the area. The EPA addressed the challenge of developing a single general permit for use across a broad range of Indian country by evaluating national EPA standards, as well as state and some local standards currently in place, and then adopting requirements we feel are appropriate and that reflect commonly used standards.

*F. Use of Throughput Limits*

1. Proposed Rule

The Federal Indian Country Minor NSR rule requires the reviewing authority to establish annual allowable emission limitations for each affected emissions unit and for each NSR regulated pollutant emitted by the unit, if the unit is issued an enforceable limitation lower than the PTE of that unit. *See* 40 CFR 49.155(a)(2). The EPA included throughput, fuel usage, and materials usage limitations and compliance monitoring requirements in the proposed general permits and permits by rule as a means for limiting emissions and demonstrating compliance with those limits. For the five source categories that are the subject of this action, some states (but not all) provide both annual ton per year allowable emission limitations and throughput limits in their general permits. Other state reviewing authorities provide only overall production limits that limit the amount of throughput a facility can process over a period of time. We requested comment on the use of throughput limits as a surrogate for ton-per-year allowable emission limitations, or, alternatively, establishment of annual allowable emission limitations for each pollutant, and the use of throughput limits as surrogate monitoring measures to demonstrate compliance with ton-per-year annual allowable emission limitations.

2. Final Action, Comments and Responses

This section provides a brief summary of significant comments received and our responses. Responses to all comments regarding this issue are set forth in Section 2.3 of the RTC Document. In our final action, we are retaining throughput limits; however, in response to comments we received, we are making adjustments to the throughput limits for the general permits for HMA plants and SQCS facilities. We believe these adjustments are appropriate for three reasons:

- They provide monthly throughput limitations to reflect the fact that HMA plants and SQCS facilities relocate often (see Section IV.A. Permit Documents and Implementation Tools);
- They provide co-located throughput limits to reflect the fact that these facilities are often sited together (see Section IV.K. Use of More Than One General Permit and/or Permit by Rule for a Source at a Single Location); and
- They ensure a margin of safety between a source's permitted throughput limit and the major source thresholds for synthetic minor sources since the general permits for these two source categories are written for use by both true minor and synthetic minor sources (see Section IV.I. Use of General Permits and Permits by Rule to Create Synthetic Minor Sources).

We are also adding a throughput limit to the GDF permit by rule for marginal and moderate ozone nonattainment areas.

The EPA received comments on the use of throughput limitations for HMA and SQCS facilities. A few commenters agreed with the throughput production limits and fuel-type and usage limits stated in the draft permits for HMA plants and SQCS facilities and believe that the emission limitations based on those factors are reasonable. One commenter asserted that the inclusion of different throughput limits in general permits for attainment versus nonattainment areas is unnecessary because each such nonattainment area will have a nonattainment state implementation plan (SIP) that, by definition, will include measures adequate to achieve attainment. The EPA disagrees that the existence of nonattainment SIPs renders the inclusion of nonattainment-area specific emission limitations unnecessary. A state's SIP may or may not account for activities in Indian country and the state may lack authority to implement or enforce the SIP there.[36] As a result, the EPA believes that establishing different throughput limits for nonattainment areas is necessary to help move such areas toward attainment.

Several commenters supported the use of throughput limits noting that monitoring throughput limits, hours of operation and production are more efficient and cost-effective methods for minor sources to demonstrate their compliance. A few commenters advocated that sources be allowed flexibility in demonstrating compliance, including using alternative methods to a throughput limit so that facility capacity is not unnecessarily constrained. A few commenters requested that the General Permit also include clearly defined, enforceable, annual allowable emission limits.

[36] In *Oklahoma Dept. of Environmental Quality* v. *EPA,* 740 F.3rd 185 (D.C. Cir. 2014), the U.S. Court of Appeals for the District of Columbia Circuit held that the state, not tribes or the EPA, has initial primary responsibility for implementation plans under Clean Air Act section 110 in non-reservation areas of Indian country (*i.e.,* dependent Indian communities and Indian allotments) in the absence of a demonstration of tribal jurisdiction by the EPA or a tribe. However, SIPs generally do not apply in reservations, including informal reservations or trust lands, and these areas are believed to comprise the bulk of Indian country.

The EPA notes that these types of permit terms and conditions are commonly found in state general permits and permits by rule. Throughput, materials usage, and hours of operation are easy to track. As a result, limitations on throughput, materials usage and hours of operation are less burdensome than requiring sources to determine emissions on a regular basis in order to demonstrate compliance with an emission limit. If a source feels an alternative limit or compliance monitoring method is more compatible with their operational procedures, they may apply for a source-specific permit to have such criteria considered.

*G. Setback Requirements*

1. Proposed Rule

For HMA plants and SQCS facilities, we included permit provisions regarding the location of the emitting activities relative to the source property boundary. We call these provisions, which are designed to minimize the near-field impacts of emissions, setback requirements. Under the proposed setback requirement, sources could not locate within a specific distance of the property boundary and nearest residences. We proposed that these provisions seemed both reasonable and prudent measures to protect local air quality and are economically feasible and cost effective.

We invited comments to identify other source categories for which setback requirements should apply. We also welcomed comments on the types of buildings from which we should establish setbacks (*e.g.,* schools, nursing homes). Lastly, we further requested comment on whether the setback requirements conflict with tribal authority over zoning-related matters, and, if so, on how we should resolve that conflict.

2. Final Action, Comments and Responses

One commenter recommended that the EPA add a setback requirement to the HMA permit similar to the one included in the proposed SQCS facilities permit. Another commenter noted that the setback requirements may be difficult for existing sources to meet if the source is modified. Due to the lack of an EPA analysis demonstrating the air quality benefits of requiring setbacks, we lack sufficient information to incorporate them in the final general permits for HMA plants and SQCS facilities. Therefore, the final general permits for HMA plants and SQCS facilities do not contain setback provisions. Nonetheless, the reviewing authority retains the discretion to deny the granting of source coverage under the general permits based on local air quality concerns. The many comments the EPA received on its inclusion of setback requirements in the SQCS and HMA permits, and our responses to those comments, are found in Sections 3.2.1.1, 3.2.1.2, 3.2.4.1, 3.3.4, and 4.2.1 of the RTC Document.

*H. Permit by Rule Regulatory Framework*

1. Proposed Rule

We proposed to codify a nationally applicable permit by rule for source categories or emissions generating activities for which we have determined that the permit by rule mechanism would offer permit streamlining benefits, while at the same time protecting air quality, into a new section of the Federal Indian Country Minor NSR rule. As proposed, permits by rule would be used to address source categories of true minor sources, where the reviewing authority does not need to conduct an in-depth review to evaluate whether an individual source meets all of the requirements in the permit. A permit by rule may be issued for a category of emissions units or sources that are similar in nature, have substantially similar emissions and would be subject to the same or substantially similar requirements governing operations, emissions, monitoring, reporting and recordkeeping. ''Similar in nature'' refers to size, processes and operating conditions. We requested comment on all aspects of the streamlined permit by rule approach.

2. Final Action, Comments and Responses

This section provides a brief summary of significant comments received. In our final action, we are codifying nationally applicable permits by rule for three source categories: GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities. Overall, as described in greater detail below, we are making two significant changes to the process or framework we proposed in January 14, 2014. First, we are requiring that sources obtain advance, written confirmation from the EPA that the screening procedures have been completed correctly for threatened and endangered species and historic properties. To provide clarification, we have created a new document, ''Procedures to Address Threatened and Endangered Species and Historic Properties for New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule,'' that sources will need to use prior to submitting a Notification of Coverage Form. Second, we are making clear the process citizens will need to follow to appeal a source's coverage under a permit by rule.

Under these three permits by rule, individual sources eligible for coverage will be subject to the operational, monitoring and recordkeeping requirements specified in the relevant rule. In this action, in addition to promulgating the three permits by rule, we are amending the Indian Country Minor NSR rule general permit provisions at 40 CFR 49.156 to set forth the unique elements of the permits by rule process. The permits by rule program establishes a more streamlined notification of coverage process that allows an individual applicant to notify the reviewing authority that it meets the eligibility criteria for the permit and the permit conditions. The source will complete the Notification of Coverage Form and submit copies of the form to both the reviewing authority and the appropriate tribal entity to satisfy the registration requirement at 40 CFR 49.160(c)(1)(iii). A copy of the completed form must be kept onsite and made available upon request. This ''notification'' process streamlines permitting for eligible sources and makes it easier for the reviewing authority to implement the permit by rule program compared to traditional site-specific permits and standard general permits.

A permit by rule must be issued according to the applicable requirements in §§ 49.154(c), 49.154(d) and 49.155. A source category permit by rule must include the permit elements listed in § 49.155(a). The reviewing authority will determine which categories of true minor sources are appropriate for coverage under a permit by rule. Permits by rule will be issued at the discretion of the reviewing authority. Issuance of a permit by rule is considered final agency action with respect to all aspects of the permit by rule except its applicability to an individual source.

Prior to submitting the Notification of Coverage Form to the reviewing authority, a source must demonstrate to the EPA that the endangered or threatened species and historic property screening procedures set forth in the procedures document [37] provided for

[37] The processes are contained in the following document: ''Procedures to Address Threatened and Endangered Species and Historic Properties for

that purpose for the permits by rule have been satisfactorily completed. The source must submit documentation of the endangered or threatened species and historic property screening evaluations to the EPA (and the tribe in the area in which the source is located/locating) for review prior to submitting the completed Notification of Coverage Form and obtaining coverage under a permit by rule. Thirty days after receipt of the documentation, the EPA must notify the source by letter of one of two possible outcomes: (a) The documentation is satisfactory (*i.e.,* the listed species and historic property screening procedures have been completed properly); or (b) the documentation is not adequate and additional information/evaluation is needed. If the initial submittal is deemed deficient, the EPA will identify any deficiencies and may offer further direction on completing the screening process(es). Once the source has addressed the noted deficiencies it must resubmit its updated screening procedure documentation to the EPA for review. The source must obtain written confirmation from the EPA indicating that it has adequately documented that the screening procedures have been properly completed before it can submit its Notification of Coverage Form.

If the source qualifies for a permit by rule and intends to notify the reviewing authority that it is covered under the rule, the source may submit its Notification of Coverage Form upon the effective date of the permit by rule, generally 60 days after publication of the permit by rule in the **Federal Register**. Pursuant to the registration requirement of § 49.160(c)(1)(iii), the source must submit a completed Notification of Coverage Form to the reviewing authority. The Notification of Coverage Forms are available online at *http://www.epa.gov/air/tribal/tribalnsr.html* or at: Docket ID No. EPA–HQ–OAR–2011–0151. The source must also submit a copy of the completed Notification of Coverage Form to the tribe in whose area of Indian country the source is locating or expanding.

Upon receiving the Notification of Coverage Form, the EPA must post the notification on its Web site. The posting of the notification form is considered final agency action with respect to its applicability to an individual source. The sole issue that may be appealed after an individual source is covered under a permit by rule is the applicability of the permit by rule to that particular source. Appeals must be made to the U.S. Court of Appeals within 60 days of EPA's action. The EPA is promulgating this process as a separate regulation from 40 CFR 49.159 to provide a process for permits by rule that is streamlined compared to the two-step process provided in 40 CFR 49.159 for general permits.

The source must comply with all terms and conditions of the permit by rule. The source will be subject to enforcement action for failure to obtain a preconstruction permit if the emissions unit(s) or source is constructed under coverage of a permit by rule and the source is later determined not to qualify under the terms and conditions of the permit by rule.

Coverage under a permit by rule becomes invalid if construction is not commenced within 18 months after the date of the posting of the completed Notification of Coverage Form under a source category permit by rule, if construction is discontinued for a period of 18 months or more, or if construction is not completed within a reasonable time. The reviewing authority may extend the 18-month period upon a satisfactory showing that an extension is justified. This provision does not apply to the time period between construction of the approved phases of a phased construction project; construction of each such phase must commence within 18 months of the projected and approved commencement date. Any source category covered by a permit by rule may also instead apply for a source-specific permit under 40 CFR 49.154.

The EPA received many comments on the regulatory framework proposed for establishing permits by rule. Summaries of all of these comments, and the EPA's responses, are found in Section 4.1 of the RTC Document. Many of these commenters supported the EPA's proposed use of permits by rule for GDFs, auto body repair and miscellaneous surface coating, and petroleum dry cleaning facilities, stating that a permit by rule is appropriate for these types of sources and that several states already use permits by rule for these source categories. A few commenters asserted that the use of permit by rule would expedite the permitting process, reduce administrative burdens and costs for permitting agencies, and allow the EPA to more efficiently manage minor sources. Two commenters expressed concerns about whether the EPA has the resources to process general permits in a timely manner, referenced issues experienced by the EPA Region 8 office when the synthetic minor source permitting program for that region became effective, and pointed to the Fort Berthold Indian Reservation FIP [38] used in that region as a model for EPA's minor source permitting. Two commenters asserted that the permit by rule approach provides sufficient opportunities for public input, as well as retaining the public's right to judicial review of any source's receipt of coverage under a permit by rule. One commenter recommended that the requirement for certification of compliance be retained in the final rule, and that the applicant be required to mail a copy of the application to the reviewing authority for the reviewing authority's records. A few commenters opposed use of permits by rule for these three source types, stating that the process does not allow for public notice and comment. Two commenters stated that a facility may not be aware of all aspects of the permitting process they must meet to comply. One commenter noted that neither the EPA nor the tribe would be able to review and confirm that a facility is providing the correct information.

After carefully considering all of the comments on these issues, the EPA concludes that permits by rule are appropriate for the following three source categories and is, therefore, finalizing them: GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities. In doing this, the EPA addresses the goal of protecting air quality, while reducing workloads of reviewing authorities and minimizing delays associated with the permitting process by providing a streamlined approach for permitting construction of less complex minor sources that have the simplest compliance requirements.

The EPA disagrees with those commenters opposing the use of permits by rule. These three source types are relatively straightforward sources (compared to HMA plants and SQCS facilities), have similar operations and can be adequately controlled with a single set of control requirements without the need for additional reviewing authority evaluation or further public notice. Requiring these facilities to seek coverage under a general permit would add to the workload of the reviewing authority

New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule,'' *http://www.epa.gov/air/tribal/tribalnsr.html.*

[38] ''Approval and Promulgation of Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota,'' U.S. Environmental Protection Agency, 78 FR 17836, March 22, 2013, *http://www.gpo.gov/fdsys/pkg/FR-2013-03-22/pdf/2013-05666.pdf.*

without providing substantial benefits to air quality since a general permit would be unlikely to impose any additional substantive requirements. Since we are establishing the permit by rule through notice and comment rulemaking, the public has had an adequate opportunity to comment on the proposed rule and the provisions of the permits by rule for the three source categories. The public retains the opportunity for judicial review on the issue of whether the source should be able to gain coverage under the permit by rule. Regarding the concern that a facility may not be aware of all aspects of the permitting process, the EPA has developed multiple implementation tools and documents to provide facilities with the information necessary to understand the permitting process, assist facilities in navigating the permitting process and help to ensure that a facility meets critical permitting requirements. The EPA is adding the requirement to submit a copy of the Notification of Coverage Form to the relevant tribal government office when notifying the reviewing authority in order to ensure that the tribal government is aware of new facilities. The EPA is also clarifying that under 40 CFR 49.160(c)(1)(iii), minor source applicants [39] (other than sources in the oil and natural gas sector) that must register with the EPA beginning on September 2, 2014, will do so by providing a copy of their minor source permit Notification of Coverage Form.

One commenter argued that the use of permits by rule would effectively mean that sources exceeding the minor source permit threshold are exempt from a permit. Another commenter asserted that permits by rule are not appropriate for either true minor or synthetic minor sources. The commenter also stated that it is difficult to enforce against a source that has constructed in violation of the ''permit by rule'' requirements. The EPA disagrees. Permits by rule are only available to true minor sources. As with source-specific permits and general permits, the permit by rule contains a set of enforceable terms and conditions that will ensure that facilities remain true minor sources. Facilities that cannot meet the throughput limitations or emission controls in the permits by rule would not be eligible for coverage. Facilities must submit a Notification of Coverage Form certifying that the facility will comply with all of the terms and conditions in the relevant permit by rule. Each permit by rule contains clear, enforceable terms and conditions such that noncompliance can quickly be identified. If a source operates in violation of the terms in a permit by rule for which the owner/operator has submitted a completed Notification of Coverage Form, the reviewing authority can revoke coverage under the permit by rule and the owner/operator may be subject to an enforcement action for failing to obtain a permit prior to commencing construction.

One commenter pointed out that the proposed rule did not include ''specific regulatory language'' for any of the proposed permits by rule, and argued that the lack of regulatory text prevented full and complete public review and comment on the proposed rule. As discussed in Section VIII (Proposed Permits by Rule) of the preamble to the proposed rule, rather than proposing separate, specific regulatory language for any of the proposed permits by rule, we proposed a general approach to issuing permits by rule and to codify the requirements of the draft general permits for the specified source category. Therefore, EPA did effectively propose specific regulatory language for each proposed permit by rule.

*I. Use of General Permits and Permits by Rule To Create Synthetic Minor Sources*

1. Proposed Rule

We proposed to allow a source to use coverage under general permits, including the permits by rule mechanism, to establish federally enforceable emission limitations that can restrict operations of an otherwise major source, such that the source qualifies as a synthetic minor source. We requested comment on all aspects of using general permits and permits by rule to create synthetic minor sources generally and with respect to the five source categories in the proposed rule. We requested specific comment on whether:

- Any regulatory changes in the permits being proposed would be necessary to implement this change in policy;
- A source should be allowed to qualify to use a general permit or permit by rule to become a synthetic minor source, and then subsequently use a general permit or permit by rule to authorize construction or modification activities;
- Both regulatory purposes can be achieved in a single general permit/permit by rule;
- Permits by rule are an appropriate type of permit for creating synthetic minor sources, given that the permit notification does not provide an opportunity for public input on the coverage of a particular source by a permit by rule;
- Any specific changes that would need to be made to the general permits to include provisions for creating synthetic minor permits for these source categories;
- Any specific changes that would need to be made in the production limits of each permit to properly regulate synthetic minor sources for these categories; and
- Permit conditions include sufficient monitoring, recordkeeping and reporting provisions to: (a) Assure continuous compliance; and (b) lower the emissions potential to that of a true minor source.

2. Final Action, Comments and Responses

In our final action, we have modified the EPA's policy on the use of general permits to create synthetic minor sources and are allowing the use of general permits to create synthetic minor sources. We have further concluded that it is not appropriate to allow the use of permits by rule to create synthetic minor sources. Consistent with EPA guidance,[40] we have set the throughput limits in the HMA and SQCS general permits at levels sufficiently low to ensure a margin of safety between a source's permitted throughput limit (and corresponding emissions) and the major source thresholds, since the general permits for these two source categories are written for use by both true minor and synthetic minor sources (see Section IV.F. Use of Throughput Limits).

The EPA received numerous comments regarding the use of general

[39] The language of 40 CFR 49.160(c)(1)(iii) refers specifically to ''applications.'' Eligible sources that have decided to be covered by a permit by rule are not required to submit applications. They are required to submit ''notification'' forms to the reviewing authority that they are electing to be covered under a permit by rule. Submittal of the Notification of Coverage Form to the reviewing authority satisfies the registration requirement.

[40] See the following memos available in the docket (ID No. EPA–HQ–OAR–2011–0151): ''Guidance on Limiting the Potential to Emit in New Source Permitting,'' from Terrell E. Hunt, Associate Enforcement Counsel, Office of Enforcement and Compliance Monitoring and John S. Seitz, Director, Office of Air Quality Planning and Standards, to EPA Regional Counsels, 1–10, et al, June 13, 1989, *http://www.epa.gov/ttn/atw/pte/june13_89.pdf*; and ''Options for Limiting the Potential to Emit (PTE) of a Stationary Source Under Section 112 and Title V of the Clean Air Act (Act),'' from John S. Seitz, Director, Office of Air Quality Planning and Standards, and Robert I. Van Heuvelen, Director, Office of Regulatory Enforcement, to Air Division Directors, EPA Regions 1–10, January 25, 1995, *http://www.epa.gov/region7/air/title5/t5memos/ptememo.pdf*.

permits and specific regulatory changes to the draft permits for each source category to address synthetic minor sources. A summary of all of these comments, and the EPA's responses, are found in Sections 5.1 and 5.3 of the RTC Document.

Many commenters supported the use of general permits or permits by rule to create synthetic minor sources. A few commenters agreed that major sources should be able to take advantage of this streamlined permitting process, noted that this process would provide an incentive for sources that would otherwise be considered a major source to voluntarily reduce emissions, and that these general permits will satisfy the air quality standards set by the NSR program. As noted, the EPA is not finalizing the use of a permit by rule to create synthetic minor sources, but will allow the use of a general permit for that purpose. Because we are finalizing general permits in this action for only two source categories (HMA plants and SQCS facilities), only general permits for these two source categories can be used to create synthetic minor sources.

Several commenters stated that the use of general permits to establish federally enforceable emissions limits will ensure that emissions from synthetic minor sources are appropriately restricted. The commenters further stated that this would result in efficiency for both operators and regulatory agencies, while leading to improved health and welfare in Indian country. A few commenters requested that the EPA provide more discussion regarding the technical process for developing a general permit, and asked how the EPA plans to address compliance with the one-hour and annual $NO_2$ NAAQS. The EPA agrees that the use of general permits to establish federally enforceable limits on PTE will ensure that emissions from synthetic minor sources are appropriately restricted. The EPA has revised the throughput limits and fuel use limits in the HMA and SQCS general permits to keep covered sources' emissions below the NSR major source thresholds, with an adequate margin to account for uncertainties of measurement, emissions from unpermitted activities, variability in emission rates, and excess emissions during startup, shutdown, or malfunction.[41] We agree with commenters that, if appropriately restricted and monitored, synthetic minor sources covered by a general permit would not pose an environmental concern and would have emissions similar to sources subject to a source-specific permit.

With respect to the $NO_2$ NAAQS, EPA conducted a control technology review that is discussed in the proposed rule (See Section V. Source Categories for Which Draft General Permits in Indian Country are Available for Public Review). The EPA believes that the final permits we are issuing and promulgating today are appropriately protective of the NAAQS (see Section IV.E. Control Technology Review). However, we reserve the ability to deny coverage under a general permit based on concerns we may have about the state of air quality in the area where a source is seeking to locate or modify, and the potential impacts of an individual source in that area.

A few commenters reiterated that case-by-case permitting determinations for source types where equipment and operations do not differ significantly from source to source is unnecessary. One commenter noted that state programs have used general permits and permits by rule to authorize synthetic minor sources, and that these permitting programs afford permittees consistency, predictability, and efficiency, while reducing the administrative burden on the permitting authority and allowing permittees of similar sites to operate on a level playing field. A few commenters pointed to the Fort Berthold FIP as an example of the successful use of general permits or permits by rule for synthetic minor permits, also noting that the requirements of the Fort Berthold FIP were consistent with the requirements of the North Dakota SIP; thus, providing a level playing field. The EPA agrees with commenters that the use of general permits to create synthetic minor sources provides consistency, predictability, and efficiency, and reduces the administrative burden on the permitting authority, while allowing for greater scrutiny in the review of the permit application by the reviewing authority. The EPA is not finalizing the use of permits by rule for synthetic minor sources because permits by rule do not provide for the same level of review and scrutiny by the reviewing authority. They also do not provide the same level of public participation. The EPA does not believe it is necessary to establish a separate general permit for the specific purpose of creating synthetic minor sources. The EPA is, therefore, providing one general permit each for the HMA and SQCS source categories that are suitable for true minor and synthetic minor sources. The EPA has balanced the need to provide a level regulatory playing field with the need to protect the NAAQS. (However, the issue does not arise for the three permit by rule source categories in this action because the permit by rule is not a suitable mechanism for creating synthetic minor sources.)

Several commenters provided support for the use of general permits to create synthetic minor sources, but opposed the use of permit by rule for this purpose, while several commenters advocated for the use of a permit by rule for synthetic minor sources. Two commenters asserted that no additional risk of noncompliance would result from the use of permits by rule for synthetic minor sources, while another commenter urged the EPA to consider using the streamlined permits for synthetic minor sources on a case-by-case basis. The EPA has determined that a permit by rule approach is not appropriate for creating synthetic minor sources. We are only allowing the use of general permits to create synthetic minor sources, which allows for greater scrutiny in the review of the permit application by the reviewing authority. This level of review helps to ensure that a particular source that would otherwise be major is likely to be able to comply with the throughput limits and emissions control requirements in the general permit, thereby ensuring that the source's emissions will be below the major source threshold(s). We believe that this level of review is necessary for sources with a PTE that would otherwise be above the major source threshold(s). Because permits by rule do not provide for the same level of review regarding coverage, we are not finalizing the use of permits by rule to create synthetic minor sources.

A few commenters urged that the EPA make regulatory changes to be more explicit and to inhibit future litigation concerning the issuance of general permits or permits by rule for synthetic minor sources, while other commenters urged the EPA to include more stringent monitoring, recordkeeping and reporting requirements so that synthetic minor sources can prove their emissions are below the major source thresholds. A few commenters supported the EPA's suggestion to issue synthetic minor permits only to sources with actual emissions at a margin below the major source thresholds. This would assure

[41] The throughput limits for the permits by rule being promulgated today are also set at levels to keep covered sources' emissions below the NSR major source thresholds. However, because the permit by rule cannot be used to create synthetic minor sources, it is not necessary to lower the throughput limits for the three source categories to reflect an added margin to account for uncertainties of measurement, emissions from unpermitted activities, variability in emission rates, and excess emissions during startup, shutdown, or malfunction.

that synthetic minor sources do not inadvertently become major sources. Several commenters disagreed, stating that the EPA should not require more stringent monitoring, recordkeeping and reporting requirements for synthetic minor sources using a general permit or permit by rule. Other commenters stated that the EPA should not impose additional requirements or limitations on the use of general permits or permits by rule for synthetic minor sources. A few commenters argued that compliance with permit limits will be required regardless of whether a source is a true or synthetic minor source, and requested that the general permits, implementation documents, and tools contained in the proposed rule be amended to allow both true and synthetic minor sources to apply for coverage. The EPA is not setting a requirement that synthetic minor permits may only be issued to sources with actual emissions at a margin below the major source thresholds, but we are requiring sources to identify whether they are a synthetic minor source in their Request for Coverage Form. In the application process, permittees could apply for a general permit for purposes of creating a synthetic minor source only if they meet the eligibility requirements and are able to comply with the federally-enforceable limits established in the general permit. Once EPA approves the Request for Coverage, the requirements in the general permit become federally-enforceable limits on the source's PTE. The monitoring, recordkeeping and reporting requirements remain the same for true minor sources and synthetic minor sources.

*J. Use of Both Permitting Mechanisms for Certain Source Categories*

1. Proposed Rule

The EPA requested comments on finalizing both permitting mechanisms for a given source category by providing authorization to construct or modify true minor sources via permits by rule and by providing enforceable limitations to create synthetic minor sources via general permits. We sought comment on whether this concept should be applied differently or the same for different source categories.

2. Final Action, Comments and Responses

The EPA has decided to not make both permit types available for any single source category largely because we have determined that none of the five source categories would be suitable candidates for both permit types. As proposed, the EPA is finalizing general permits for the HMA and SQCS source categories, but is not finalizing permits by rule because the EPA does not believe that true minor sources in these two source categories are good candidates for permits by rule. For the other three source categories in today's final action, the EPA is finalizing only permits by rule because we do not believe that it is necessary to provide general permits for these categories as the potential impacts of emissions from sources in these categories can be readily addressed through a permit by rule. We believe that the majority of sources in the three source categories in this action for which we are promulgating permits by rule are not major sources and, therefore, would not need to seek synthetic minor status. However, any source in these three source categories that performs a PTE analysis and determines it is a major source can seek synthetic minor source status through a site-specific permit.

The EPA received comments regarding finalizing both permitting mechanisms (general permits and permits by rule) for GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities. Summaries of all of these comments and our responses to them are contained in Section 5.2 of the RTC Document.

While one commenter supported the establishment of both permitting mechanisms for these three source types, several commenters opposed the EPA's proposed ''hybrid approach'' to establishing permits by rule for true minor sources and general permits for synthetic minor sources. Several commenters suggested that permits by rule would work as well as a general permit for any source category, and that the EPA should accordingly treat true and synthetic minor sources for all source categories in the same manner. As noted, the EPA is not adopting a hybrid approach of establishing general permits for synthetic minor sources and permits by rule for true minor sources. The EPA does not anticipate that these three source types would require a synthetic minor permit or that a hybrid approach would be necessary.

*K. Use of More Than One General Permit and/or Permit by Rule for a Source at a Single Location*

1. Proposed Rule

As proposed, the intent of this minor source permitting process is to ensure that a single stationary source gains coverage under a general permit or permit by rule only if its PTE is below major source emission levels. We requested comment on whether to allow a single stationary source to gain coverage under more than one general permit or permit by rule. We also requested comment on whether we should categorically decline to allow coverage under more than one general permit or permit by rule for a single stationary source, or whether the application/notification materials offer the EPA an adequate opportunity to verify that source-wide PTE for a stationary source is below major source levels.

2. Final Action, Comments and Response

The EPA received comments related to the use of more than one general permit or permit by rule for a source at a single location. Summaries of all of these comments and our responses to them are contained in Section 5.4 of the RTC Document. In this final action, as discussed in detail below, we are retaining the approach in our proposal on calculating PTE emissions for permit eligibility purposes, and we are adjusting the throughput limits in the HMA and SQCS general permits to accommodate cases of co-location for those two source categories.

Several commenters supported allowing the use of more than one general permit or permit by rule for a single source with different types of equipment or co-located processes. One commenter asserted that co-located sources should not be precluded from using general permits if site-wide emissions remain below major source thresholds. A few commenters expressed concerns with allowing a synthetic minor source to acquire coverage under more than one general permit or permit by rule, as it could potentially allow a source to incrementally increase emissions and avoid major NSR preconstruction review and other regulatory requirements. Other commenters disagreed, asserting that there is no basis in the rulemaking record for assuming that the use of more than one general permit or permit by rule might allow a source to increase emissions beyond regulatory requirements. Several commenters contended that a permit by rule for larger, more complex sources, or synthetic minor sources would not provide for adequate review by a reviewing authority, and suggested including a requirement to report total emissions to prove the source is in compliance.

The EPA is finalizing its proposed policy with respect to a source gaining coverage under multiple general permits

or permits by rule with modifications. Under the proposed policy, to qualify for a general permit or permit by rule a source must sum the PTE of its new, modified and existing units. If that sum is below major source thresholds, the source is a true minor source and is eligible for a true minor source general permit or permit by rule, provided it can meet the permits' throughput limits and other terms and conditions (even if the source is already subject to an existing general permit/permit by rule). In this final action, we also allow the same steps for synthetic minor sources seeking a general permit. In both cases, the agency reserves the ability to deny a general permit for synthetic minor sources seeking to combine new emissions with existing emissions if the reviewing authority has concerns about local air quality conditions.

In addition, we have modified the general permit applications for HMA plants and SQCS facilities so as to allow those source types to co-locate, if desired. If the applicant is seeking such co-location, the permit contains the option to comply with alternative throughput limits set low enough to ensure the source's emissions are below the level that would trigger the requirement to obtain a title V permit.

*L. Additional Source Categories for General Permits and/or Permits by Rule*

1. Proposed Rule

In developing the proposal, the EPA solicited input from tribal governments and the EPA Regional Offices on which source categories should be covered by streamlined permitting in Indian country. The tribes and the EPA Regional Offices identified the five source categories addressed in the proposed action because they were thought to be common in Indian country and were good potential candidates for streamlined permitting for several reasons: They represent categories of emissions units or stationary sources that are similar in nature, have substantially similar emissions, and would be subject to the same or substantially similar permit requirements.[42] The following source categories were also thought to be good candidates for streamlined permitting:

- Printing operations (including solvent cleaning/degreasing);
- Engines (spark and compression ignition);
- Concrete batch plants;
- Saw mills;
- Landfill operations;
- Boilers; and
- Oil and gas production and operations.

We requested comment on whether the additional source categories identified above should receive coverage by general permits or permits by rule, including comments as to which categories are appropriate for each type of rule. With respect to landfill operations, the EPA specifically requested comment on whether enough landfill activity is occurring in Indian country to warrant the development of a general permit or permit by rule. In connection with the EPA's Municipal Solid Waste Landfills New Source Performance Standard (40 CFR 60.750, subpart WWW), the EPA created a database of active landfills across the U.S. using information from the EPA's Greenhouse Gas Reporting Program,[43] Landfill Methane Outreach Program, and Information Collection Request Center. The database indicates there is a very small number of landfills in Indian country. These results were compared to the source culling that we did with the National Emissions Inventory and the lists of sources from Regions 5 and 10, which also showed few landfills in Indian country. Based on this information, we indicated that we were not convinced that the resources necessary to develop a general permit or permit by rule for landfills would be justified and requested comment on the issue.[44]

2. Final Action, Comment and Response

The EPA received comments related to additional source categories for which general permits or permits by rule might be appropriate. Summaries of all of those comments and our responses to them are contained in Sections 6.1, 6.2, 6.3, and 6.4 of the RTC Document. The EPA received several comments in support of the use of general permits or permits by rule for minor sources for engines, concrete batch plants, saw mills, boilers, printing operations, and landfills, and only one comment in opposition. Aside from landfill operations, the source categories discussed in this section are being addressed in separate actions. In particular, in July 2014, the EPA proposed a combination of general permits and permits by rule for spark ignition engines, compression ignition engines, saw mills, graphic arts and printing operations, boilers, and concrete batch plants, but not for landfills.[45] A review of the available data for landfills in Indian country indicates that there are a limited number of these sources in Indian country, and we do not expect this to change. As a result, we do not think that the establishment of a general permit or permit by rule for this source category is warranted.

The EPA received numerous comments supporting the development of general permits or permits by rule for the oil and natural gas source category, noting that these permits offer operators a level of certainty regarding permitting requirements, will reduce emissions, and will decrease regulatory burdens for sources and regulators. A few commenters also expressed support for the use of general permits or permits by rule for synthetic minor sources in the oil and natural gas source category, because the facilities and emission controls do not significantly vary from site to site. The EPA has determined that permitting for sources in the oil and natural gas source category should be dealt with in a separate action because of the unique characteristics of those sources. Accordingly, in May 2014, the EPA issued an ANPR to solicit input on potential permitting approaches to address emissions from new, modified and existing oil and natural gas production activities. The EPA will consider the comments received in response to the original January 14, 2014, proposed rule concerning the permitting of minor oil and natural gas sources in Indian country in the action it will take as a follow up to the ANPR.

*M. Final Rule Changes to the Federal Indian Country Minor NSR Rule*

1. Proposed Rule

In the January 14, 2014, notice, we proposed five changes to three separate provisions in the existing Federal Indian Country Minor NSR rule to ensure the smooth functioning of the general permit program:

(a) Shortening the general permit application review process from 90 to 45 days for certain source categories (§ 49.156(e)(4));

(b) Adjusting the deadline by which minor sources covered by a general

[42] "Review of New Sources and Modifications in Indian Country," U.S. Environmental Protection Agency, 76 FR 38770, July 1, 2011, *https://www.federalregister.gov/articles/2011/07/01/2011-14981/review-of-new-sources-and-modifications-in-indian-country.*

[43] For more information, go to: *http://www.epa.gov/ghgreporting/index.html.*

[44] The results of this analysis can be found at Docket ID No. The EPA–HQ–OAR–2011–0151 and online at *http://www.epa.gov/air/tribal/tribalnsr.html.*

[45] "General Permits and Permits by Rule for the Federal Minor New Source Review Program in Indian Country," U.S. Environmental Protection Agency, 79 FR 41846, July 17, 2014, *http://www.gpo.gov/fdsys/pkg/FR-2014-07-17/pdf/2014-16814.pdf.*

permit need to obtain a preconstruction permit (§ 49.151(c)(1)(iii)(B));

(c) Extending the permitting deadline for true minor sources within the oil and gas source category (§ 49.151(c)(1)(iii)(B));

(d) Removing a provision to make it clear that sources may seek coverage under a general permit as soon as it is effective and need not wait an additional four months (§ 49.156(e)(1)); and

(e) Adjusting the deadline for oil and natural gas sources for certain registration related requirements to be consistent with the proposed permitting deadline extension (§ 49.160(c)(1)(ii) and (iii)).

We proposed the first change for three source categories: GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities.

2. Final Action, Comments and Responses

On June 16, 2014, EPA issued final amendments [46] addressing three of the changes:

- Adjusted the deadline by which minor sources covered by a general permit need to obtain a preconstruction permit by eliminating a requirement for all true minor sources that begin operation before September 2, 2014, to obtain a minor NSR permit 6 months after the EPA publishes a general permit (no general permits were finalized by May 2014, so the provision was moot) (§ 49.151(c)(1)(iii)(B)) (pertains to item (b) under above Section 1. Proposed Rule);
- Extended the permitting deadline for true minor sources within the oil and gas source category (§ 49.151(c)(1)(iii)(B)) (pertains to item (c) under above Section 1. Proposed Rule); and
- Adjusted the deadline for oil and gas sources for certain registration-related requirements to be consistent with the proposed permitting deadline extension (§ 49.151(c)(1)(iii)(A)) and § 49.160(c)(1)(ii) and (iii)) (pertains to item (e) under above Section 1. Proposed Rule).

The comments received on these changes were addressed in the June 16, 2014, **Federal Register** notice.

In today's final action, we are addressing the two other proposed changes:

- Shortening the general permit application review process from 90 to 45 days for certain source categories (§ 49.156(e)(4)) (pertains to item (a) under above Section 1. Proposed Rule); and
- Removing a provision to make clear that sources may seek coverage under a general permit as soon as it is effective and need not wait an additional 4 months (§ 49.156(e)(1)) (pertains to item (d) under above Section 1. Proposed Rule).

The first change is now moot because we are finalizing permits by rule for the three source categories in question (except that the GDF permit by rule does not cover California); the permit by rule process does not include an application review. We are addressing the second change by amending § 49.156(e)(1) to make the general permits available as soon as they are effective, which is generally 60 days after signature. In addition, we have added a provision to ensure that this is also true for permits by rule that we promulgate.

The EPA received comments related to these two changes. Summaries of all comments and our responses are contained in Section 7.0 of the RTC Document. Several commenters supported the EPA's proposal to amend § 49.156(e)(1) so that minor sources would not be required to wait four months to seek coverage under the general permit after the general permit's effective date, but may seek coverage as soon as the general permit is effective. The EPA is removing the requirement for sources to wait four months after the general permit is finalized to request coverage. The EPA also received a number of comments related to shortening the general permit application review process from 90 to 45 days for certain source categories. Multiple commenters supported the EPA's proposal to shorten the general permit application review process from 90 to 45 days for 3 of the proposed source categories (GDFs, auto body repair and miscellaneous surface coating operations, and petroleum dry cleaning facilities). A few commenters recommended that the EPA consider reducing the application review period for general permits to 30 days. As noted, the EPA is not finalizing revisions to § 49.156(e)(4) to shorten the General Permit application review process from 90 to 45 days for the permits for the GDF, auto body repair and miscellaneous surface operations, or petroleum dry cleaning source categories because we are not issuing general permits for those source categories. Rather, we are establishing permits by rule, for which there is no review process for these three source categories.

We are promulgating a minor amendment to § 49.151(c)(1)(iii)(B) by adding the words ''permit by rule'' after general permit to ensure that it is clear that the permit by rule option is available to true minor sources required to obtain a minor source permit. The section reads as follows with the added amendatory words ''/permit by rule'':

''If your true minor source is not an oil and natural gas source and you wish to begin construction of a new true minor source or a modification at an existing true minor source on or after September 2, 2014, you must first obtain a permit pursuant to §§ 49.154 and 49.155 (or a general permit/permit by rule pursuant to § 49.156, if applicable). If your true minor source is an oil and natural gas source and you wish to begin construction of a new true minor source or a modification at an existing true minor source on or after March 2, 2016, you must first obtain a permit pursuant to §§ 49.154 and 49.155 (or a general permit/permit by rule pursuant to § 49.156, if applicable). The proposed new source or modification will also be subject to the registration requirements of § 49.160, except for sources that are subject to § 49.138.''

Finally, we are promulgating a minor amendment to § 49.156 by adding the words ''permits by rule'' after general permits to ensure that it is clear that the section also contains requirements for permit by rule. The introductory paragraph to the section reads as follows with the added amendatory words ''/permits by rule'':

''This section applies to general permits/permits by rule for the purposes of complying with the preconstruction permitting requirements for sources of regulated NSR pollutants under this program.''

## V. Statutory and Executive Order Reviews

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

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

### *B. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA. This action merely establishes general permits and/or permits by rule to satisfy the requirements of the Federal Indian Country Minor NSR rule. Such permits are already available in

[46] ''Review of New Sources and Modifications in Indian Country Amendments to the Registration and Permitting Deadlines for True Minor Sources,'' U.S. Environmental Protection Agency, 79 FR 34231, June 16, 2014, *http://www.gpo.gov/fdsys/pkg/FR-2014-06-16/pdf/2014-14030.pdf.*

many states. It does not impose any new obligations or enforceable duties on any state, local or tribal government or the private sector. Therefore, this action does not impose an information collection burden. OMB has previously approved the information collection activities in the permits in this action, which are contained in the Information Collection Request for Federal Indian Country Minor NSR rule issued in July 2011 (OMB Control No. 2060–0003).

*C. Regulatory Flexibility Act*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. The EPA analyzed the impact of streamlined permitting on small entities in the Federal Indian Country Minor NSR rule (76 FR 38748, July 1, 2011). The EPA determined that that action would not have a significant economic impact on a substantial number of small entities. Today's action merely implements a particular aspect of the Federal Indian Country Minor NSR rule. As such, this action will not have a significant economic impact on a substantial number of small entities. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

*D. Unfunded Mandates Reform Act*

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

*E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. The EPA has conducted outreach on this rule via on-going monthly meetings with tribal environmental professionals in the development of this final action. This action reflects tribal comments on and priorities for developing general permits and permits by rule in Indian country. The EPA offered consultation to elected tribal officials immediately after proposal on December 16, 2013, via letter to 566 tribes to provide an opportunity for meaningful and timely input into the development of this regulation. No tribal officials requested consultation on this action.

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

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

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

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

*I. National Technology Transfer and Advancement Act*

The final action involves technical standards. The EPA has decided to use the EPA Methods 5, 7E and 10. While for the proposal the agency identified 13 voluntary consensus standards (ASME B133.9–1994 (2001), ISO 9096:1992 (2003), ANSI/ASME PTC–38–1980 (1985), ASTM D3685/D3685M–98 (2005), CAN/CSA Z223.1–M1977, ANSI/ASME PTC 19–10–1981—Part 10, ISO 10396:1993 (2007), ISO 12039:2001, ASTM D5835–95 (2007), ASTM D6522–00 (2005), CAN/CSA Z223.2–M86 (1999), CAN/CSA Z223.21–M1978, ASTM D3162–94 (2005)) as being potentially applicable, we are not finalizing these in this rulemaking. The use of these voluntary consensus standards would not be practical with applicable law due to a lack of equivalency, documentation, validation data and other important technical and policy considerations. The EPA did not receive comments that have caused us to alter the standards and methods in the final permits.

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

The EPA believes the human health or environmental risk addressed by this action will not have potentially, disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action does not affect the level of protection provided to human health or the environment. This final rule merely implements certain aspects of the Federal Indian Country Minor NSR rule. Therefore, this final action will not have a disproportionately high and adverse human health or environmental effects on minorities, low-income, indigenous populations in the United States.

Our primary goal in developing this program is to ensure that air resources in Indian country will be protected in the manner intended by the CAA. This Rule will reduce adverse impacts by improving air quality in Indian country. In addition, we seek to establish a flexible preconstruction permitting program for minor sources in Indian country that is comparable to similar programs in neighboring states in order to create a more level regulatory playing field for owners and operators within and outside of Indian country. This Rule will reduce an existing disparity by filling the regulatory gap.

*K. Congressional Review Act*

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 49**

Environmental protection, Administrative practices and procedures, Air pollution control, Indians, Indians-law, Indians-tribal government, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: April 17, 2015.

**Gina McCarthy,**

*Administrator.*

For the reasons stated in the preamble, title 40, Chapter 1 of the Code of Federal Regulations is amended as follows:

## PART 49—INDIAN COUNTRY: AIR QUALITY PLANNING AND MANAGEMENT

■ 1. The authority citation for part 49 continues to read as follows:

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

## Subpart C—General Federal Implementation Plan Revisions

■ 2. Section 49.151 is amended by revising paragraph (c)(1)(iii)(B) to read as follows:

### § 49.151 Program overview.

* * * * *

(c) * * *

(1) * * *

(iii) * * *

(B) If your true minor source is not an oil and natural gas source and you wish to begin construction of a new true minor source or a modification at an existing true minor source on or after September 2, 2014, you must first obtain a permit pursuant to §§ 49.154 and 49.155 (or a general permit/permit by rule pursuant to § 49.156, if applicable). If your true minor source is an oil and natural gas source and you wish to begin construction of a new true minor source or a modification at an existing true minor source on or after March 2, 2016, you must first obtain a permit pursuant to §§ 49.154 and 49.155 (or a general permit/permit by rule pursuant to § 49.156, if applicable). The proposed new source or modification will also be subject to the registration requirements of § 49.160, except for sources that are subject to § 49.138.

* * * * *

■ 3. Section 49.156 is amended by revising the section heading, the introductory text, and paragraph (e)(1), and by adding paragraph (f) to read as follows:

### § 49.156 General permits and permits by rule.

This section applies to general permits/permits by rule for the purposes of complying with the preconstruction permitting requirements for sources of regulated NSR pollutants under this program.

(e) * * *

(1) If your source qualifies for a general permit, you may submit a Request for Coverage under that general permit to the reviewing authority upon the effective date of the general permit, generally 60 days after publication of the general permit in the **Federal Register**.

* * * * *

(f) *Permits by rule overview*—(1) *What is a permit by rule?* A permit by rule is a preconstruction permit issued by a reviewing authority that may be applied to a number of similar emissions units or sources within a designated category. The purpose of a permit by rule is to simplify the permit issuance process for similar facilities so that a reviewing authority's limited resources need not be expended for case-by-case permit development for such facilities. A permit by rule may be written to address a single emissions unit, a group of the same type of emissions units or an entire minor source. A source wishing to operate pursuant to a permit by rule must submit a Notification of Coverage Form to the reviewing authority prior to commencing construction or modification. Once a source submits the Notification of Coverage and the EPA posts it online, the source may commence construction or modification without further action by the reviewing authority.

(2) *When and where does a permit by rule apply?* The provisions of a permit by rule established under the authority of this section apply on reservations and other areas of Indian country for which a tribe, or EPA acting in a tribe's stead, has demonstrated that a tribe has jurisdiction and where there is no EPA-approved tribal minor NSR program and according to the following implementation schedule: Sources that qualify for a permit by rule and have completed and submitted to the reviewing authority and the tribe in the affected area that is covered under the permit by rule the required Notification of Coverage may commence construction of a new source or modification of an existing source after the reviewing authority has posted the Notification of Coverage Form online. If your source qualifies for a permit by rule, you may submit a Notification of Coverage Form under that permit by rule upon the effective date of the permit by rule, generally 60 days after publication of the permit by rule in the **Federal Register**.

(3) *How will the reviewing authority issue permits by rule?* The reviewing authority will issue permits by rule as follows:

(i) A permit by rule may be issued for a category of emissions units or sources that are similar in nature, have substantially similar emissions and would be subject to the same or substantially similar requirements governing operations, emissions, monitoring, reporting and recordkeeping. ''Similar in nature'' refers to size, processes and operating conditions.

(ii) A permit by rule must be issued according to the applicable requirements in §§ 49.154(c) and (d) and 49.155.

(4) *For what source categories will source category permits by rule be issued?* (i) The reviewing authority will determine at its discretion which categories of true minor sources are appropriate for coverage under a permit by rule.

(ii) Permits by rule will be issued at the discretion of the reviewing authority. Issuance of a permit by rule is considered final agency action with respect to all aspects of the permit by rule except its applicability to an individual source. Permits by rule for additional source categories may be added in the future following the procedure set forth in paragraph (e)(3)(ii) of this section.

(iii) Permits by rule are currently available for the following source categories:

(A) Auto body repair and miscellaneous surface coating operations (§ 49.162).

(B) Petroleum dry cleaning facilities (§ 49.163).

(C) Gasoline dispensing facilities (§ 49.164).

(5) *What should the permit by rule contain?* A source category permit by rule must include the permit elements listed in § 49.155(a).

(6) *What procedures must you follow to obtain coverage for your source under a permit by rule?*

(i) You must determine whether your source is a true minor source by following the procedures outlined in § 49.153.

(ii) If you determine your source is a true minor source, then to be eligible to be covered by the permit you must be willing to accept the terms and conditions of the permit by rule, including emissions limits that are either directly expressed as limits or specified as an operational throughput limit or threshold.

(iii) Prior to submitting a completed Notification of Coverage to the reviewing authority notifying the reviewing authority that you are covered under a permit by rule, you must first submit documentation to the EPA (and to the tribe where the source is located/locating) demonstrating that you have completed the screening processes specified for consideration of threatened

and endangered species and historic properties and receive a determination from the EPA stating that you have satisfactorily completed these processes. (The processes are contained in the following document: ''Procedures to Address Threatened and Endangered Species and Historic Properties for New or Modified True Minor Sources in Indian Country Seeking Air Quality Permits by Rule,'' *http://www.epa.gov/air/tribal/tribalnsr.html.*) Within 30 days of receipt of your documentation, by letter to you, the reviewing authority must provide a determination that: The documentation satisfactorily demonstrates completion of the threatened and endangered species and historic property processes; or the documentation is not adequate and additional information is needed. If the initial submittal is deficient, the reviewing authority will note any such deficiencies and may offer further direction on completing the screening process(es). Once you have addressed the noted deficiencies you must resubmit your threatened and endangered species and historic property screening procedure documentation for review. An additional 15-day review notification period will be used for the reviewing authority to determine whether the ESA/NHPA screening procedures have been satisfied. If they have, the reviewing authority will send you a letter so stating. You must obtain a letter from the reviewing authority indicating that the source has adequately completed the processes regarding threatened and endangered species and historic properties is necessary before you can qualify for coverage under the permit by rule.

(iv) If your source qualifies for a permit by rule and you choose to be covered under it, following notification from the EPA that you have satisfactorily completed the threatened and endangered species and historic property processes correctly, you may submit a Notification of Coverage to the reviewing authority beginning upon the effective date of the permit by rule, generally 60 days after publication of the permit by rule in the **Federal Register**. Submission of the completed Notification of Coverage to the reviewing authority satisfies the registration requirement of § 49.160(c)((1)(iii). The necessary forms for submitting a Notification of Coverage are available online at *http://www.epa.gov/air/tribal/tribalnsr.html.* You must also submit a copy of the Notification of Coverage to the tribe in the area where your source is locating or modifying.

(v) Upon receiving your Notification of Coverage, the notification will be posted on the reviewing authority's Web site, which is the relevant EPA Regional Office's Web site unless a tribe has been delegated authority to implement the Federal Minor NSR Program in Indian Country rule. The posting of the Notification of Coverage Form is considered final agency action with respect to the permit by rule's applicability to an individual source. Appeals can only be made regarding the applicability of the permit by rule to an individual source or modification. Appeals must be made to the relevant U.S. Court of Appeals within 60 days of the EPA's final action.

(vi) Your source must comply with all terms and conditions of the relevant permit by rule. You will be subject to enforcement action for failure to obtain a preconstruction permit if the emissions unit(s) or source are constructed under coverage of a permit by rule and your source is later determined not to qualify for that permit by rule.

(vii) Coverage under a permit by rule becomes invalid if construction is not commenced within 18 months after the date of the posting of the Notification of Coverage under a source category permit by rule, if construction is discontinued for a period of 18 months or more, or if construction is not completed within a reasonable time. The reviewing authority may extend the 18-month period upon a satisfactory showing that an extension is justified. This provision does not apply to the time period between construction of the approved phases of a phased construction project; construction of each such phase must commence within 18 months of the projected and approved commencement date.

(viii) Any source eligible to request coverage under a permit by rule may instead choose to apply for a source specific permit under § 49.154 if they prefer not to be subject to the permit by rule's terms and conditions.

■ 4. Section 49.162 is added to read as follows:

**§ 49.162 Air quality permit by rule for new or modified true minor source auto body repair and miscellaneous surface coating operations in Indian country.**

(a) *Abbreviations and acronyms:*

CAA or the Act Federal Clean Air Act
cc cubic centimeters
CFR Code of Federal Regulations
CO Carbon Monoxide
EPA United States Environmental Protection Agency
g/L grams per liter
lb/gal pounds per gallon
MSDS Material Safety Data Sheet
NAAQS National Ambient Air Quality Standards
$NO_X$ Oxides of Nitrogen
NSR New Source Review
PSD Prevention of Significant Deterioration
VOC Volatile Organic Compounds

(b) *Definitions for the purposes of this permit by rule*—(1) *Adhesion promoter* means a coating, which is labeled and formulated to be applied to uncoated plastic surfaces to facilitate bonding of subsequent coatings, and on which, a subsequent coating is applied.

(2) *Airless and air-assisted airless spray* mean any paint spray technology that relies solely on the fluid pressure of the paint to create an atomized paint spray pattern and does not apply any atomizing compressed air to the paint before it leaves the paint nozzle. Air-assisted airless spray uses compressed air to shape and distribute the fan of atomized paint, but still uses fluid pressure to create the atomized paint.

(3) *Cause* means with respect to the reviewing authority's ability to terminate a permitted source's coverage under a permit by rule that:

(i) The permittee is not in compliance with the provisions of this permit by rule;

(ii) The reviewing authority determines that the emissions resulting from the construction or modification of the permitted source significantly contribute to NAAQS violations, which are not adequately addressed by the requirements in this permit by rule;

(iii) The reviewing authority has reason to believe that the permittee obtained coverage under the permit by rule by fraud or misrepresentation; or

(iv) The permittee failed to disclose a material fact required by the Notification of Coverage or the requirements applicable to the permitted source of which the applicant had or should have had knowledge at the time the permittee submitted the Notification of Coverage.

(4) *Clear coating* means any coating that contains no pigments and is labeled and formulated for application over a color coating or clear coating.

(5) *Cold cleaning solvent makeup* means the gallons of gross cold cleaning solvent usage minus the gallons of solvent disposed of as waste solvent.

(6) *Construction* means any physical change or change in the method of operation including fabrication, erection, installation, demolition, or modification of an affected emissions unit that would result in a change of emissions.

(7) *Color coating* means any pigmented coating, excluding adhesion

promoters, primers, and multi-color coatings, that requires a subsequent clear coating and which is applied over a primer or adhesion promoter. Color coatings include metallic/iridescent color coatings.

(8) *Electrostatic application* means any method of coating application where an electrostatic attraction is created between the part to be coated and the atomized paint particles.

(9) *Freeboard area* means the air space in a batch-loaded cold cleaner that extends from the liquid surface to the top of the tank.

(10) *Freeboard height* means the distance from the top of the solvent to the top of the tank for batch-loaded cold cleaners.

(11) *Freeboard ratio* means the ratio of the solvent cleaning machine freeboard height to the smaller interior dimension (length, width, or diameter) of the solvent cleaning machine.

(12) *Halogenated Hazardous Air Pollutant (HAP) solvent means* methylene chloride (CAS No. 75–09–2), perchloroethylene (CAS No. 127–18–4), trichloroethylene (CAS No. 79–01–6), 1,1,1-trichloroethane (CAS No. 71–55–6), carbon tetrachloride (CAS No. 56–23–5), and/or chloroform (CAS No. 67–66–3).

(13) *High-volume, low-pressure (HVLP) spray equipment* means spray equipment that is permanently labeled as such and used to apply any coating by means of a spray gun which is designed and operated between 0.1 and 10 pounds per square inch gauge (psig) air atomizing pressure measured dynamically at the center of the air cap and at the air horns.

(14) *Liquid leak* means a VOC-containing liquid leak from the degreaser at a rate of three drops per minute or more or any visible liquid mist.

(15) *Multi-color coating* means any coating that exhibits more than one color in the dried film after a single application, is packaged in a single container, and hides surface defects on areas of heavy use, and which is applied over a primer or adhesion promoter.

(16) *Notification of Coverage* means the permit notification that contains all the information required in the standard notification form for this permit by rule.

(17) *One-component coating* means a coating that is ready for application as it comes out of its container to form an acceptable dry film. A thinner necessary to reduce the viscosity is not considered a component.

(18) *Permittee* means the owner or operator of a permitted source.

(19) *Permitted source* means each auto body repair and miscellaneous surface coating operation for which a source submits a complete Notification of Coverage.

(20) *Pretreatment coating* means any coating that contains a minimum of one-half (0.5) percent acid by weight and not more than 16 percent solids by weight necessary to provide surface etching and is labeled and formulated for application directly to bare metal surfaces to provide corrosion resistance and adhesion.

(21) *Primer* means any coating, which is labeled and formulated for application to a substrate to provide:

(i) A bond between the substrate and subsequent coats;

(ii) Corrosion resistance;

(iii) A smooth substrate surface; or

(iv) Resistance to penetration of subsequent coats, and on which a subsequent coating is applied.

Primers may be pigmented.

(22) *Responsible official* means one of the following:

(i) For a corporation: A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is directly responsible for the overall operation of the permitted source.

(ii) For a partnership or sole proprietorship: A general partner or the proprietor, respectively.

(iii) For a public agency: Either a principal executive officer or ranking elected official, such as a chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency.

(23) *Single-stage coating* means any pigmented automotive coating, (excluding automotive adhesion promoters, primers and multi-color coatings), specifically labeled and formulated for application without a subsequent clear coating and that are applied over an adhesion promoter, a primer, or a color coating. Single-stage coatings include single-stage metallic/iridescent coatings.

(24) *Spray-applied coating operations* means coatings that are applied using a hand-held device that creates an atomized mist of coating and deposits the coating on a substrate. For the purposes of this permit by rule, spray-applied coatings do not include the following materials or activities:

(i) Coatings applied from a hand-held device with a paint cup capacity that is equal to or less than 3.0 fluid ounces (89 cc).

(ii) Surface coating application using powder coating, hand-held, non-refillable aerosol containers, or non-atomizing application technology, including, but not limited to, paint brushes, rollers, hand wiping, flow coating, dip coating, electro deposition coating, web coating, coil coating, touch-up markers, or marking pens.

(iii) Thermal spray operations (also known as metalizing, flame spray, plasma arc spray, and electric arc spray, among other names) in which solid metallic or non-metallic material is heated to a molten or semi-molten state and propelled to the work piece or substrate by compressed air or other gas, where a bond is produced upon impact.

(25) *Temporary protective coating* means any coating which is labeled and formulated for the purpose of temporarily protecting areas from overspray or mechanical damage.

(26) *Tire retread adhesive means* any adhesive to be applied to the back of pre-cured tread rubber and to the casing and cushion rubber, or to be used to seal buffed tire casings to prevent oxidation while the tire is being prepared for a new tread.

(27) *Truck bed liner* coating means any coating, excluding color, multi-color, and single stage coatings, labeled and formulated for application to a truck bed to protect it from surface abrasion.

(28) *Two-component coating* means a coating requiring the addition of a separate reactive resin, commonly known as a catalyst, before application to form an acceptable dry film.

(29) *Underbody coating* means any coating labeled and formulated for application to wheel wells, the inside of door panels or fenders, the underside of a trunk or hood, or the underside of the motor vehicle.

(30) *Uniform finish coating* means any coating labeled and formulated for application to the area around a spot repair for the purpose of blending a repaired area's color or clear coat to match the appearance of an adjacent area's existing coating.

(31) *Volatile organic compounds or VOC* means any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions. This does not include the compounds listed in 40 CFR 51.100(s)(1).

(c) *Information about this permit by rule.* (1) Applicability. Pursuant to the provisions of the Clean Air Act (CAA), subchapter I, part D and 40 CFR part 49, subpart C, this permit authorizes the construction or modification and the

operation of the auto body repair and miscellaneous surface coating operation for which a reviewing authority receives a completed Notification of Coverage (permitted source).

(2) *Eligibility.* To be eligible for coverage under this permit by rule, the permitted source must qualify as a true minor source as defined in 40 CFR 49.152 and satisfied the requirements in 40 CFR 49.156(f)(6)(iii).

(3) *Notification of Coverage.* Requirements for submitting a Notification of Coverage are contained in paragraph (d)(1) of this section. The information contained in each permitted source's Notification of Coverage is hereby enforceable under this permit by rule.

(4) *Termination.* Paragraph (d)(6) of this section addresses a reviewing authority's ability to revise, revoke and reissue, or terminate coverage under this permit by rule. It also addresses the reviewing authority's ability to terminate an individual permitted source's coverage under this permit by rule.

(5) *Definitions.* The terms used herein shall have the meaning as defined in 40 CFR 49.152, unless otherwise defined in paragraph (b) of this section. If a term is not defined, it shall be interpreted in accordance with normal business use.

(d) *Permit by rule terms and conditions.* The following applies to each permittee and permitted source with respect to only the affected emissions units and any associated air pollution control technologies in that permitted source's Notification of Coverage.

(1) *General provisions*—(i) *Obtaining coverage under this permit by rule.* To obtain coverage under this permit by rule, an applicant must submit a completed Notification of Coverage to the appropriate reviewing authority for the area in which the permitted source is or will be located (the Notification of Coverage Form can be found at: *http://www.epa.gov/air/tribal/tribalnsr.html*). Table 2 contains a list of reviewing authorities and their area of coverage. You must also submit a copy of the Notification of Coverage to the Indian governing body for any area in which the permitted source will operate in Indian country.

(ii) *Construction and operation.* The permittee shall construct or modify and shall operate the affected emissions units and any associated air pollution control technologies in compliance with this permit by rule and all other applicable federal air quality regulations; and in a manner consistent with representations made by the permittee in the Notification of Coverage.

(iii) *Location.* This permit by rule only authorizes the permittee to construct or modify and to operate the permitted source in the location listed in the Notification of Coverage for that permitted source.

(iv) *Liability.* This permit by rule does not release the permittee from any liability for compliance with other applicable federal and tribal environmental laws and regulations, including the CAA.

(v) *Severability.* The provisions of this permit by rule are severable. If any portion of this permit by rule is held invalid, the remaining terms and conditions of this permit by rule shall remain valid and in force.

(vi) *Compliance.* The permittee must comply with all provisions of this permit by rule, including emission limitations that apply to the affected emissions units at the permitted source. Noncompliance with any permit by rule provision is a violation of the permit by rule and may constitute a violation of the CAA; is grounds for an enforcement action; and is grounds for the reviewing authority to revoke and terminate the permitted source's coverage under this permit by rule.

(vii) *National Ambient Air Quality Standards (NAAQS)/Prevention of Significant Deterioration (PSD) Protection.* The permitted source must not cause or contribute to a NAAQS violation or, in an attainment area, must not cause or contribute to a PSD increment violation.

(viii) *Unavailable defense.* It is not a defense for the permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the provisions of this permit by rule.

(ix) *Property rights.* This permit by rule does not convey any property rights of any sort or any exclusive privilege.

(x) *Information requests.* You, as the permittee, shall furnish to the reviewing authority, within 30 days unless another timeframe is specified by the EPA, any information that the reviewing authority may request in writing to determine whether cause exists for revising, revoking and reissuing, or terminating coverage under the permit by rule or to determine compliance with the permit by rule. For any such information claimed to be confidential, the permittee must submit a claim of confidentiality in accordance with 40 CFR part 2, subpart B.

(xi) *Inspection and entry.* Upon presentation of proper credentials, the permittee must allow a representative of the reviewing authority to:

(A) Enter upon the premises where a permitted source is located or emissions-related activity is conducted or where records are required to be kept under the conditions of the permit by rule;

(B) Have access to and copy, at reasonable times, any records that are required to be kept under the conditions of the permit by rule;

(C) Inspect, during normal business hours or while the permitted source is in operation, any facilities, equipment (including monitoring and air pollution control equipment), practices or operations regulated or required under the permit by rule;

(D) Sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit by rule or other applicable requirements; and

(E) Record any inspection by use of written, electronic, magnetic and photographic media.

(xii) *Posting of coverage.* The most current Notification of Coverage for the permitted source must be posted prominently at the facility, and each affected emissions unit and any associated air pollution control technology must be labeled with the identification number listed in the Notification of Coverage for that permitted source.

(xiii) *Duty to obtain source-specific permit.* If the reviewing authority intends to terminate a permitted source's coverage under this permit by rule for cause as provided in § 49.162(d)(6), then the permittee shall apply for and obtain a source-specific permit as required by the reviewing authority.

(xiv) *Credible evidence.* For the purpose of establishing whether the permittee violated or is in violation of any requirement of this permit by rule, nothing shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether a permitted source would have been in compliance with applicable requirements if the permittee had performed the appropriate performance or compliance test or procedure.

(2) *Emission limitations and standards.* (i) The permittee shall install, maintain, and operate each affected emissions unit, including any associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions of NSR regulated pollutants and considering the manufacturer's recommended operating

procedures at all times, including periods of startup, shutdown, maintenance and malfunction. The reviewing authority will determine whether the permittee is using acceptable operating and maintenance procedures based on information available to the reviewing authority which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection of the permitted source.

(ii) The permittee shall not use volatile organic compound (VOC) containing materials (*e.g.,* coatings, thinners, and clean-up solvents) in excess of the following amounts (solvent used in a cold cleaning solvent degreaser does not count toward compliance with this limit):

(A) 5,000 gallons per year based on a 12-month rolling total for facilities located in ozone attainment, unclassifiable or attainment/unclassifiable areas; and

(B) 900 gallons per year based on a 12-month rolling total for facilities located in ozone nonattainment areas.

(iii) Total annual cold cleaning solvent makeup shall not exceed 500 gallons in any 12-month period.

(iv) The total combined heat input capacity of all combustion units (such as space heaters or ovens) shall not exceed 10 MMBtu/hr. The combustion units shall only burn natural gas, propane, or butane.

(v) Each combustion unit rated at 2.0 MMBtu/hr or greater located in a serious, severe, or extreme ozone nonattainment area shall meet the following requirements:

(A) $NO_X$ emissions shall not exceed 30 $ppm_{dv}$ at 3 percent oxygen or 0.011 lb/MMBtu based on a 15-minute average.

(B) CO emissions shall not exceed 400 $ppm_{dv}$ at 3 percent oxygen or 0.30 lb/MMBtu based on a 15-minute average.

(vi) The capacity of any volatile liquid storage tank shall not exceed 19,812 gallons.

(vii) Except as specified in paragraph (d)(2)(xv) of this section, the VOC content of coatings, as applied, shall not exceed 8.34 pounds of VOC per gallon (999.4 grams of VOC per liter).

(viii) All painters must have certification that they have completed training in the proper spray application of surface coatings and the proper setup and maintenance of spray equipment. The minimum requirements for training and certification are described in paragraph (f) of this section. The spray application of surface coatings by persons who are not certified as having completed the training described in paragraph (f) of this section is prohibited. This condition does not apply to the students of an accredited surface coating training program who are under the direct supervision of an instructor who meets the requirements of this condition.

(ix) All spray-applied coating operations must be applied in a spray booth, preparation station, or mobile enclosure that meets the following standards:

(A) All spray booths, preparation stations, and mobile enclosures must be equipped with an exhaust filter certified by the manufacturer to achieve at least 98 percent capture of paint overspray. The procedure used to demonstrate filter efficiency must be consistent with the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Method 52.1, ''Gravimetric and Dust-Spot Procedures for Testing Air-Cleaning Devices Used in General Ventilation for Removing Particulate Matter, June 4, 1992.'' The test coating for measuring filter efficiency shall be a high solids bake enamel delivered at a rate of at least 135 grams per minute from a conventional (non-HVLP) air-atomized spray gun operating at 40 pounds per square inch (psi) air pressure; the air flow rate across the filter shall be 150 feet per minute. Owners and operators may use published filter efficiency data provided by filter vendors to demonstrate compliance with this requirement and are not required to perform this measurement. The requirements of this paragraph do not apply to water wash spray booths that are operated and maintained according to the manufacturer's specifications.

(B) Spray booths and preparation stations used to refinish complete motor vehicles or mobile equipment must be fully enclosed with a full roof and four complete walls or complete side curtains, and must be ventilated at negative pressure so that air is drawn into any openings in the booth walls or preparation station curtains. However, if a spray booth is fully enclosed and has seals on all doors and other openings and has an automatic pressure balancing system, it may be operated at up to, but not more than, 0.05 inches water gauge positive pressure.

(C) Spray booths and preparation stations that are used to coat miscellaneous parts and products or vehicle subassemblies must have a full roof, at least three complete walls or complete side curtains, and must be ventilated so that air is drawn into the booth. The walls and roof of a booth may have openings, if needed, to allow for conveyors and parts to pass through the booth during the coating process.

(D) Mobile ventilated enclosures within the site that are used to perform spot repairs must enclose and, if necessary, seal against the surface around the area being coated such that paint overspray is retained within the enclosure and directed to a filter to capture paint overspray.

(E) The exhaust filters of spray booths shall be equipped with pressure gauges that indicate, in inches of water, the static pressure differential across the exhaust filters.

(F) Each spray booth located in a serious, severe, or extreme ozone nonattainment area that uses greater than 4 gallons per day of VOC-containing material shall install add-on controls (with greater than or equal to 90 percent collection efficiency and greater than or equal to 95 percent destruction efficiency) or use material with less than 5 percent VOC by weight or low VOC materials that result in an equivalent emission reduction.

(x) Except for serious, severe, and extreme ozone nonattainment areas, all spray-applied coating operations must be applied with a high volume, low pressure (HVLP) spray gun, electrostatic application, airless spray gun, or air-assisted airless spray gun. An equivalent spray technology may be used if it that has been demonstrated by the spray gun manufacturer to achieve a transfer efficiency comparable to that of an HVLP spray gun and for which the spray gun manufacturer has obtained written approval from the U.S. Environmental Protection Agency (EPA). The requirements of this condition do not apply to spray guns with a cup capacity less than 3.0 fluid ounces (89 cc).

(xi) In serious, severe, and extreme ozone nonattainment areas, all spray-applied coating operations must be applied with an HVLP spray gun, low volume low pressure (LVLP) spray gun, or air brush spray operation. An equivalent spray technology may be used if it has been demonstrated by the spray gun manufacturer to achieve a transfer efficiency comparable to that of an HVLP spray gun and for which the spray gun manufacturer has obtained written approval from the EPA.

(xii) All paint spray gun cleaning must be done so that an atomized mist or spray of gun cleaning solvent and paint residue is not created outside of a container that collects used gun cleaning solvent. Spray gun cleaning may be done with, for example, hand cleaning of parts of the disassembled gun in a container of solvent, by flushing solvent through the gun

without atomizing the solvent and paint residue, or by using a fully enclosed spray gun washer. A combination of non-atomizing methods may also be used.

(xiii) All VOC-containing material (*e.g.,* coatings, thinners, and clean-up solvents) shall be stored in closed containers.

(xiv) All waste materials containing VOC (*e.g.,* soiled rags) shall be stored in sealed containers until properly disposed.

(xv) Each permitted source located in a serious, severe, or extreme ozone nonattainment area, shall not apply a coating that has VOC content in excess of the limits listed in the Table 1 below. Compliance with the VOC limits shall be based on VOC content, including any VOC material added to the original coating supplied by the manufacturer, less water.

TABLE 1—VOC CONTENT LIMITS

| Type of coating | VOC content limits (grams/liter) | VOC content limits (lb/gallon) |
|---|---|---|
| Adhesion Promoter | 540 | 4.5 |
| Clear Coating | 250 | 2.1 |
| Color Coating | 420 | 3.5 |
| Multi-Color Coating | 680 | 5.7 |
| Pretreatment | 660 | 5.5 |
| Primer | 250 | 2.1 |
| Single-Stage Coating | 340 | 2.8 |
| Temporary Protective Coating | 60 | 0.5 |
| Truck Bed Liner Coating | 310 | 2.6 |
| Underbody Coating | 430 | 3.6 |
| Uniform Finishing Coating | 540 | 4.5 |
| One or Two-Component Coatings for Plastics | 120 | 1.0 |
| Tire Retread Adhesive | 100 | 0.8 |
| Any other coating type or adhesive | 250 | 2.1 |

(xvi) For each batch-loaded cold cleaner degreaser, the permittee shall comply with the requirements of paragraph (e) of this section.

(xvii) Each permitted source located in a serious, extreme, or severe ozone nonattainment area, shall use cleaning materials in the batch-loaded cold cleaner degreaser that have a VOC content of less than 25 grams per liter.

(3) *Monitoring and testing requirements*—(i) *Initial performance tests.* (A) Within 60 days after achieving the maximum production rate at which the permitted source will operate the affected emissions unit(s), but not later than 180 days after the first day of operation under the permit by rule, the permittee shall perform an initial performance test to verify compliance with the emission limitations in paragraphs (d)(2)(v) and (d)(2)(ix)(F) of this section (including capture efficiency requirements), if applicable. Performance tests shall be performed:

(*1*) According to a test plan submitted at least 30 days in advance of the test date to the reviewing authority;

(*2*) While the permitted source is operating under typical operating conditions;

(*3*) Using test methods from 40 CFR part 60, appendix A. In lieu of the test methods from 40 CFR part 60, appendix A, measurements for $NO_X$ and CO may be taken using portable analyzers according to ASTM D6522–00, as incorporated by reference in 40 CFR 63.14(b)(27);

(*4*) Using Method 5 with a sample volume of at least 31.8 dscf to determine particulate matter concentration; and

(*5*) Simultaneously for CO and $NO_X$ whenever either one needs to be tested.

(B) Compliance with each limit shall be demonstrated by averaging the results of at least three test runs of at least 1 hour duration each, unless the permittee can demonstrate to the satisfaction of the reviewing authority that the result of one of the test runs should be discarded. The test results the permittee submits must contain at least two test runs.

(ii) The permitted source shall demonstrate compliance with the paint overspray capture efficiency requirements of paragraph (d)(2)(ix)(A) of this section using published filter efficiency data provided by filter vendors, as described in paragraph (d)(2)(ix)(A) of this section.

(iii) The permitted source shall install, operate, and maintain an exhaust filter pressure gauge on each spray booth and monitor (in inches of water) the static pressure differential across the exhaust filter at least once per calendar month while the equipment is operating. As necessary, the exhaust filter shall be replaced according to the manufacturer's specifications.

(iv) The exterior of each spray booth, preparation station, or mobile enclosure shall be inspected at least once per calendar month for evidence of overspray. If evidence of overspray is apparent, the permittee shall take corrective action to eliminate overspray from the exterior of each spray booth, preparation station, or mobile enclosure.

(v) Prior to each use, each cold solvent cleaning degreaser shall be inspected for liquid leaks, visible tears, or cracks.

(4) *Recordkeeping requirements.* (i) The permittee shall maintain all records required to be kept by this permit by rule onsite for at least 5 years from the date of origin of the record, unless otherwise stated.

(ii) The Notification of Coverage and all documentation supporting the notification shall be maintained by the permittee for the duration of time the affected emissions unit(s) is covered under this permit by rule.

(iii) The permittee shall keep records of the VOC-containing materials (including coatings, thinners, and clean-up solvents) as follows:

(A) The name and Material Safety Data Sheet (MSDS) for each VOC-containing material used onsite; and

(B) The gallons of each VOC-containing material used each month and the resulting 12-month rolling total of VOC-containing material used. The 12-month rolling total is defined as the sum of the VOC material used during the current month and the VOC material used for the previous 11 months.

(C) For each permitted source located in a serious, severe, or extreme ozone nonattainment area *not* complying with the control requirements in paragraph (d)(2)(ix)(F) of this section (add-on controls or low VOC-containing

material), the combined daily gallons of VOC-containing material used in all spray booths.

(iv) The permittee shall keep records of the VOC content (g/L or lb/gal) for each coating material used onsite.

(v) For each spray booth, preparation station, and mobile enclosure, the permittee shall maintain records of:

(A) The filter efficiency of the exhaust material;

(B) The monthly exhaust filter pressure gauge readings specified in § 49.162(d)(3)(iii);

(C) The date when each exhaust filter is replaced;

(D) Any corrective actions taken to reduce overspray; and

(E) The results of any corrective actions taken.

(vi) The permittee shall maintain documentation from the spray gun manufacturer that each spray gun meets the requirements of paragraphs (d)(2)(x) and (xi) of this section, as applicable. For a spray gray that uses equivalent technology, documentation that the spray gun has been determined by the EPA to achieve a transfer efficiency equivalent to that of an HVLP spray gun is required.

(vii) For each cold cleaning solvent degreaser, the permittee shall:

(A) Maintain records of owner's manuals, or if not available, written maintenance and operating procedures; and

(B) Maintain a log of any actions taken to repair leaks, tears or cracks and the results of the corrective action taken.

(viii) The permittee shall maintain records of the MSDS for each solvent used in a solvent degreaser.

(ix) The permittee shall maintain records of the gallons of cold cleaning solvent makeup used each calendar month and a total of the number of gallons of cold cleaning solvent makeup used in each 12-month period.

(x) The results of each performance test conducted pursuant to paragraph (d)(3)(i) of this section shall be recorded. At a minimum, the permittee shall maintain records of:

(A) The date of each test;

(B) Each test plan;

(C) Any documentation required to approve an alternate test method;

(D) The results of each test;

(E) The name of the company or entity conducting the analysis; and

(F) Test conditions.

(5) *Notification and reporting requirements*—(i) *Notification of construction or modification, and operations.* The permittee shall submit a written or electronic notice to the reviewing authority within 30 days from when the permittee begins actual construction, and within 30 days from when the permittee begins initial operations or resumes operations after a modification.

(ii) *Notification of change in ownership or operator.* If the permitted source changes ownership or operator, then the new owner must submit a written or electronic notice to the reviewing authority within 90 days before or after the change in ownership is effective. In the notice, the new permittee must provide the reviewing authority a written agreement containing a specific date for transfer of ownership, and an effective date on which the new owner assumes partial and/or full coverage and liability under this permit by rule. The submittal must identify the previous owner, and update the name, street address, mailing address, contact information, and any other information about the permitted source if it would change as a result of the change of ownership. The current owner shall ensure that the permitted source remains in compliance with the permit by rule until any such transfer of ownership if effective.

(iii) *Notification of closure.* The permittee must submit a report of any permanent or indefinite closure to the reviewing authority in writing within 90 days after the cessation of all operations at the permitted source. The notification must identify the owner, the current location, and the last operating location of the permitted source. It is not necessary to submit a report of closure for regular, seasonal closures.

(iv) *Annual reports.* The permittee shall submit an annual report on or before March 15 of each calendar year to the reviewing authority. The annual report shall cover the period from January 1 to December 31 of the previous calendar year and shall include:

(A) An evaluation of the permitted source's compliance status with the requirements in paragraph (d)(2) of this section;

(B) Summaries of the required monitoring and recordkeeping above in paragraphs (d)(3) and (4) of this section; and

(C) Summaries of deviation reports submitted pursuant to paragraph (d)(5)(v) of this section.

(v) *Deviation reports.* The permittee shall promptly report to the reviewing authority any deviations as defined at 40 CFR 71.6(a)(3)(iii)(C) from permit by rule requirements including deviations attributable to upset conditions. (For the purposes of this permit by rule, *promptly* shall be defined to mean: At the time the annual report in § 49.162(d)(5)(iv) is submitted.) Deviation reports shall include:

(A) The identity of the affected emissions unit(s) where the deviation occurred;

(B) The nature of the deviation;

(C) The length of time of the deviation;

(D) The probable cause of the deviation; and

(E) Any corrective actions or preventive measures taken as a result of the deviation to minimize emissions from the deviation and to prevent future deviations.

(vi) *Performance test reports.* The permittee shall submit a test report to the reviewing authority within 45 days after the completion of any required performance test. At a minimum, the test report shall include:

(A) A description of the affected emissions unit and sampling location(s);

(B) The time and date of each test;

(C) A summary of test results, reported in units consistent with the applicable standard;

(D) A description of the test methods and quality assurance procedures used;

(E) A summary of any deviations from the proposed test plan and justification for why the deviation(s) was necessary;

(F) The amount of fuel burned, raw material consumed, and product produced during each test run;

(G) Operating parameters of the affected emissions units and control equipment during each test run;

(H) Sample calculations of equations used to determine test results in the appropriate units; and

(I) The name of the company or entity performing the analysis.

(vii) *Reporting and notification address.* The permittee shall send all required reports to the reviewing authority at the mailing address specified in paragraph (g) of this section.

(viii) *Signature verifying truth, accuracy and completeness.* All reports required by this permit by rule shall be signed by a responsible official as to the truth, accuracy and completeness of the information. The report must state that, based on information and belief formed after reasonable inquiry, the statements and information are true, accurate, and complete. If the permittee discovers that any reports or notification submitted to the reviewing authority contain false, inaccurate, or incomplete information, the permittee shall notify the reviewing authority immediately and correct or amend the report as soon as practicable.

(6) *Changes to this permit by rule*—(i) *Revising, reopening, revoking and reissuing, or terminating for cause.* The permit by rule may be revised,

reopened, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit revision, revocation and re-issuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit by rule condition. This provision also applies to the documents incorporated by reference.

(ii) *Terminating coverage under this permit by rule.* The reviewing authority may terminate coverage under the permit by rule, and thereby terminate that permittee's authorization to construct or modify, and that permitted source's authorization to operate under this permit by rule for cause as defined in paragraph (b) of this section. The reviewing authority may provide the permittee with notice of the intent to terminate, and delay the effective date of the termination to allow the permittee to obtain a source-specific permit as required by the reviewing authority.

(iii) *Permit becomes invalid.* Authority to construct and operate under this permit by rule becomes invalid if the permittee does not commence construction within 18 months after the notification of coverage is received by the reviewing authority, if the permittee discontinues construction for a period of 18 months or more, or if the permittee does not complete construction within a reasonable time. The reviewing authority may extend the 18-month period upon a satisfactory showing that an extension is justified, according to 40 CFR 49.156(e)(8).

(e) *Standards for batch-loaded cold cleaner degreasers.* (1) Each degreaser shall be operated in accordance with the manufacturer's specifications and shall be used with tightly fitting covers that are free of cracks, holes, or other defects. In addition, the cover shall be closed at all times when the degreaser contains solvent, except during parts entry and removal or performing maintenance or monitoring that requires the removal of the cover.

(2) The solvent container shall be free of all liquid leaks. Auxiliary degreaser equipment, such as pumps, water separators, steam traps, or distillation units, shall not have any liquid leaks, visible tears, or cracks. In addition, any liquid leak, visible tear, or crack detected pursuant to the provisions of this condition shall be repaired within 48 hours, or the degreaser shall be drained of all solvent and shut down until replaced or repaired.

(3) All waste solvents shall be stored in properly identified and sealed containers. All associated pressure relief devices shall not allow liquid solvents to drain out.

(4) Solvent flow cleaning shall be done within the freeboard area, and shall be done by a liquid stream rather than a fine, atomized, or shower-type spray. Solvent flow shall be directed downward to avoid turbulence at the air-solvent interface and to prevent liquid solvent from splashing outside of the degreaser.

(5) Degreasing of porous or absorbent materials, such as cloth, leather, wood, or rope is prohibited.

(6) Workspace and ventilation fans shall not be positioned in such a way as to direct airflow near the degreaser openings.

(7) Spills during solvent transfer shall be wiped up immediately and the used wipe rags shall be stored in closed containers that are handled in accordance with paragraph (e)(3) of this section.

(8) Solvent levels shall not exceed the fill line.

(9) The parts to be cleaned shall be racked in a manner that will minimize the drag-out losses.

(10) The freeboard ratio shall be 0.75 or greater. Parts shall be drained immediately after the cleaning until at least 15 seconds have elapsed; or dripping of solvent ceases; or the parts become visibly dry. Parts with blind holes or cavities shall be tipped or rotated before being removed from a degreaser, such that the solvents in the blind holes or cavities are drained in accordance with the above requirements.

(11) Draining or filling of solvent containers shall be performed beneath the liquid solvent surface.

(12) Solvent agitation, where necessary, shall be carried out only by pump recirculation, ultrasonics, a mixer, or by air agitation. Air agitation shall be accomplished under the following conditions:

(i) The air agitation unit shall be equipped with a gauge and a device that limits air pressure into the degreaser to less than two pounds per square inch gauge;

(ii) The cover must remain closed while the air agitation system is in operation; and

(iii) Pump circulation shall be performed without causing splashing.

(13) Airless/Air-tight Cleaning System Requirements—In lieu of meeting the requirements of paragraphs (e)(1) through (12) of this section, the permittee may use an airless/air-tight batch cleaning system provided that all of the following applicable requirements are met:

(i) The equipment is operated in accordance with the manufacturer's specifications and operated with a door or other pressure sealing apparatus that is in place during all cleaning and drying cycles.

(ii) All waste solvents are stored in properly identified and sealed containers.

(iii) All associated pressure relief devices shall not allow liquid solvents to drain out.

(iv) Spills during solvent transfer shall be wiped up immediately, and the used wipe rags shall be stored in closed containers that are handled in accordance with paragraph (e)(3) of this section.

(v) The equipment is maintained in a vapor-tight, leak-free condition and any leak is a violation.

(f) *Training and certification requirements for spray-applied surface coating personnel.* The owner or operator of the permitted source must ensure and certify that all new and existing personnel, including contract personnel, who spray apply surface coatings are trained in the proper application of surface coatings as required by this permit by rule. The training program must include, at a minimum, the items listed in this paragraph (f). All personnel must be trained no later than 180 days after hiring.

(1) A list of all current personnel by name and job description who are required to be trained.

(2) Hands-on and classroom instruction that addresses, at a minimum, initial and refresher training in the following topics:

(i) Spray gun equipment selection, set up, and operation, including measuring coating viscosity, selecting the proper fluid tip or nozzle, and achieving the proper spray pattern, air pressure and volume, and fluid delivery rate.

(ii) Spray technique for different types of coatings to improve transfer efficiency and minimize coating usage and overspray, including maintaining the correct spray gun distance and angle to the part, using proper banding and overlap, and reducing lead and lag spraying at the beginning and end of each stroke.

(iii) Routine spray booth and filter maintenance, including filter selection and installation.

(iv) Compliance with the requirements of this Permit by Rule.

(3) A description of the methods to be used at the completion of initial or refresher training to demonstrate, document, and provide certification of successful completion of the required training. Owners and operators who can

show by documentation or certification that a painter's work experience and/or training has resulted in training equivalent to the training required in paragraph (f)(2) of this section are not required to provide the initial training required by that same paragraph to the painter.

(4) Painter training that was completed within 5 years prior to the date training is required, and that meets the requirements specified in paragraph (f)(2) of this section satisfies this requirement and is valid for a period not to exceed 5 years after the date the training was completed.

(5) Training and certification will be valid for a period not to exceed 5 years after the date the training is completed, and all personnel must receive refresher training that meets the requirements of this § 49.162(f) and be re-certified every 5 years.

(g) *List of reviewing authorities and areas of coverage.*

TABLE 2—LIST OF REVIEWING AUTHORITIES AND AREAS OF COVERAGE

| EPA region | Address for notification of coverage | Address for all other notification and reports | Area covered | Phone number |
|---|---|---|---|---|
| Region I | EPA New England, 5 Post Office Square, Suite 100, Mail Code OEP05–2, Boston, MA 02109–3912. | EPA New England, 5 Post Office Square, Suite 100, Mail Code OES04–2, Boston, MA 02109–3912. | Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. | 888–372–7341 617–918–1111 |
| Region II | Chief, Air Programs Branch, Clean Air and Sustainability Division, EPA Region 2, 290 Broadway, 25th Floor, New York, NY 10007–1866. | Chief, Air Compliance Branch, Division of Enforcement and Compliance Assistance, EPA Region 2, 290 Broadway, 21st Floor, New York, NY 10007–1866. | New Jersey, New York, Puerto Rico, and Virgin Islands. | 877–251–4575 |
| Region III | Office of Permits and Air Toxics, 3AP10, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. | Office of Air Enforcement and Compliance Assurance, 3AP20, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. | Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. | 800–438–2474 215–814–5000 |
| Region IV | Chief, Air Permits Section, EPA Region 4 APTMD, 61 Forsyth Street, Atlanta, GA 30303. | Chief, Air & EPCRA Enforcement Branch, EPA Region 4 APTMD, 61 Forsyth Street, SW, Atlanta, GA 30303. | Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. | 800–241–1754 404–562–9000 |
| Region V | Air Permits Section, Air Programs Branch (AR–18J), EPA Region 5, 77 West Jackson Blvd, Chicago, Illinois 60604. | Air Enforcement and Compliance Assurance Branch (AE–17J), Air and Radiation Division, EPA Region 5, 77 West Jackson Blvd, Chicago, IL 60604. | Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. | 800–621–8431 312–353–2000 |
| Region VI | Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue (6PD–R), Dallas, TX 75202. | Compliance and Enforcement Correspondence: Compliance Assurance and Enforcement Division, EPA Region 6, 1445 Ross Avenue (6EN), Dallas, TX 75202. | Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. | 800–887–6063 214–665–2760 |
| Region VII | Chief, Air Permitting & Compliance Branch, EPA Region 7, 11201 Renner Blvd, Lenexa, KS 66219. | Chief, Air Permitting & Compliance Branch, EPA Region 7, 11201 Renner Blvd, Lenexa, KS 66219. | Iowa, Kansas, Missouri, and Nebraska. | 800–223–0425 913–551–7003 |
| Region VIII | U.S. Environmental Protection Agency, Region 8, Office of Partnerships and Regulatory Assistance, Tribal Air Permitting Program, 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202. | U.S. Environmental Protection Agency, Region 8, Office of Enforcement, Compliance & Environmental Justice, Air Toxics and Technical Enforcement Program, 8ENF–AT, 1595 Wynkoop Street, Denver, CO 80202. | Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. | 800–227–8917 303–312–6312 |
| Region IX | Chief, Permits Office (Air-3), Air Division, EPA Region 9, 75 Hawthorne St, San Francisco, CA 94105. | Enforcement Division Director, Attn: Air & TRI Section (ENF–2–1), EPA Region 9, 75 Hawthorne St, San Francisco, CA 94105. | American Samoa, Arizona, California, Guam, Hawaii, Navajo Nation Nevada, and Northern Mariana Islands. | 866–EPA–9378 415–947–8000 |
| Region X | Tribal Air Permits Coordinator, U.S. EPA, Region 10, AWT–150, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. | Tribal Air Permits Coordinator, U.S. EPA, Region 10, AWT–150, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. | Alaska, Idaho, Oregon, and Washington. | 800–424–4372 206–553–1200 |

■ 5. Section 49.163 is added to read as follows:

**§ 49.163 Air quality permit by rule for new or modified true minor source petroleum dry cleaning facilities in Indian country.**

(a) *Abbreviations and acronyms:*

CAA or the Act—Federal Clean Air Act
CFR—Code of Federal Regulations
EPA—United States Environmental Protection Agency
NAAQS—National Ambient Air Quality Standards
NSR—New Source Review
PSD—Prevention of Significant Deterioration

(b) *Definitions for the purposes of this permit by rule*—(1) *Cause* means with respect to the reviewing authority's ability to terminate a permitted source's coverage under a permit that:

(i) The permittee is not in compliance with the provisions of this permit by rule;

(ii) The reviewing authority determines that the emissions resulting from the construction or modification of the permitted source significantly contribute to National Ambient Air Quality Standard violations, which are not adequately addressed by the requirements in this permit by rule;

(iii) The reviewing authority has reason to believe that the permittee obtained coverage under the permit by rule by fraud or misrepresentation; or

(iv) The permittee failed to disclose a material fact required by the Notification of Coverage or the requirements applicable to the permitted source of which the applicant had or should have had knowledge at the time the permittee submitted the Notification of Coverage.

(2) *Construction* means any physical change or change in the method of operation including fabrication, erection, installation, demolition, or modification of an affected emissions unit that would result in a change of emissions.

(3) *Notification of Coverage* means the permit notification that contains all of the information required in the standard notification form for this permit by rule.

(4) *Permittee* means the owner or operator of a permitted source.

(5) *Permitted source* means each petroleum drying cleaning facility for which a source submits a complete Notification of Coverage.

(6) *Responsible official* means one of the following:

(i) For a corporation: A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is directly responsible for the overall operation of the permitted source.

(ii) For a partnership or sole proprietorship: A general partner or the proprietor, respectively.

(iii) For a public agency: Either a principal executive officer or ranking elected official, such as a chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency.

(7) *Solvent recovery dryer* means a class of dry cleaning dyers that employs a condenser to condense and recovery solvent vapors evaporated in a closed-loop stream of heated air, together with the piping and ductwork used in the installation of this device.

(c) *Information about this permit by rule*—(1) *Applicability.* Pursuant to the provisions of the Clean Air Act (CAA), subchapter I, part D and 40 CFR part 49, subpart C, this permit by rule authorizes the construction or modification and the operation of each stationary petroleum dry cleaning facility for which a reviewing authority receives a completed Notification of Coverage (permitted source).

(2) *Eligibility.* To be eligible for coverage under this permit by rule, the permitted source must qualify as a true minor source as defined in 40 CFR 49.152 and satisfied the requirements in 40 CFR 49.156(f)(6)(iii).

(3) *Notification of Coverage.* Requirements for submitting a Notification of Coverage are contained in paragraph (d)(1) of this section. The information contained in each permitted source's Notification of Coverage is hereby enforceable under this permit by rule.

(4) *Termination.* Paragraph (d)(6) of this section addresses a reviewing authority's ability to revise, revoke and reissue, or terminate coverage under this permit by rule. It also addresses the reviewing authority's ability to terminate an individual permitted source's coverage under this permit by rule.

(5) *Definitions.* The terms used herein shall have the meaning as defined in 40 CFR 49.152, unless otherwise defined in paragraph (b) of this section. If a term is not defined, it shall be interpreted in accordance with normal business use.

(d) *Permit by rule terms and conditions.* The following applies to each permittee and permitted source with respect to only the affected emissions units and any associated air pollution control technologies in that permitted source's Notification of Coverage.

(1) *General provisions*—(i) *Obtaining coverage under this permit by rule.* To obtain coverage under this permit by rule, an applicant must submit a completed Notification of Coverage to the appropriate reviewing authority for the area in which the permitted source is or will be located (the Notification of Coverage Form can be found at: *http://www.epa.gov/air/tribal/tribalnsr.html*). Table 1 of paragraph (f) of this section contains a list of reviewing authorities and their area of coverage. You must also submit a copy of the Notification of Coverage to the Indian governing body for any area in which the permitted source will operate.

(ii) *Construction and operation.* The permittee shall construct or modify and shall operate the affected emissions units and any associated air pollution control technologies in compliance with this permit by rule and all other applicable federal air quality regulations; and in a manner consistent with representations made by the permittee in the Notification of Coverage.

(iii) *Locations.* This permit by rule only authorizes the permittee to construct or modify and to operate the permitted source at the location listed in the Notification of Coverage for that permitted source.

(iv) *Liability.* This permit by rule does not release the permittee from any liability for compliance with other applicable federal and tribal environmental laws and regulations, including the CAA.

(v) *Severability.* The provisions of this permit by rule are severable. If any portion of this permit by rule is held invalid, the remaining terms and conditions of this permit by rule shall remain valid and in force.

(vi) *Compliance.* The permittee must comply with all provisions of this permit, including emission limitations that apply to the affected emissions units at the permitted source. Noncompliance with any permit by rule provision is a violation of the permit by rule and may constitute a violation of the CAA; is grounds for an enforcement action; and is grounds for the reviewing authority to revoke and terminate the permitted source's coverage under this permit by rule.

(vii) *National Ambient Air Quality Standards (NAAQS)/Prevention of Significant Deterioration (PSD) Protection.* The permitted source must not cause or contribute to a NAAQS violation or, in an attainment area, must not cause or contribute to a PSD increment violation.

(viii) *Unavailable defense.* It is not a defense for the permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the provisions of this permit by rule.

(ix) *Property rights.* The permit by rule does not convey any property rights of any sort or any exclusive privilege.

(x) *Information requests.* You, as the permittee, shall furnish to the reviewing authority, within 30 days unless another timeframe is specified by the EPA, any information that the reviewing authority may request in writing to determine whether cause exists for revising, revoking and reissuing, or terminating coverage under the permit by rule or to determine compliance with the permit by rule. For any such information claimed to be confidential, the permittee must submit a claim of confidentiality

in accordance with 40 CFR part 2, subpart B.

(xi) *Inspection and entry.* Upon presentation of proper credentials, the permittee must allow a representative of the reviewing authority to:

(A) Enter upon the premises where a permitted source is located or emissions-related activity is conducted or where records are required to be kept under the conditions of the permit by rule;

(B) Have access to and copy, at reasonable times, any records that are required to be kept under the conditions of the permit by rule;

(C) Inspect, during normal business hours or while the permitted source is in operation, any facilities, equipment (including monitoring and air pollution control equipment), practices or operations regulated or required under the permit by rule;

(D) Sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit by rule or other applicable requirements; and

(E) Record any inspection by use of written, electronic, magnetic and photographic media.

(xii) *Posting of coverage.* The most current Notification of Coverage for the permitted source must be posted prominently at the facility, and each affected emissions unit and any associated air pollution control technology must be labeled with the identification number listed in the Notification of Coverage for that permitted source.

(xiii) *Duty to obtain a source-specific permit.* If the reviewing authority intends to terminate a permitted source's coverage under this permit by rule for cause as provided in § 49.163(d)(6), then the permittee shall apply for and obtain a source-specific permit as required by the reviewing authority.

(xiv) *Credible evidence.* For the purpose of establishing whether the permittee violated or is in violation of any requirement of this permit by rule, nothing shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether a permitted source would have been in compliance with applicable requirements if the permittee had performed the appropriate performance or compliance test or procedure.

(2) *Emission limitations and standards.* (i) The permittee shall install, maintain, and operate each affected emissions unit, including any associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions of NSR regulated pollutants and considering the manufacturer's recommended operating procedures at all times, including periods of startup, shutdown, maintenance and malfunction. The reviewing authority will determine whether the permittee is using acceptable operating and maintenance procedures based on information available to the reviewing authority which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection of the permitted source.

(ii) The permittee shall not consume more than the amount of petroleum solvent specified below:

(A) 5,600 gallons per year based on a rolling 12-month total for a facility located in an ozone attainment, unclassifiable or attainment/unclassifiable area; or

(B) 1,300 gallons per year based on a rolling 12-month total for a facility located in an ozone nonattainment area.

(iii) If your facility has a total manufacturer's rated dryer capacity equal to or greater than 38 kilograms (84 pounds), then you shall meet the following requirements:

(A) Each petroleum solvent dry cleaning dryer shall be a solvent recovery dryer. The solvent recovery dryer(s) shall be properly installed, operated and maintained according to the manufacturer's specifications.

(B) Each petroleum solvent dry cleaning dryer located in a serious, severe or extreme ozone nonattainment area shall be a closed loop, dry-to-dry machine with a refrigerated condenser (manufacture red on or after October 20, 2000) or with an evaporatively cooled condenser (manufacture red on or after July 9, 2004.)

(iv) The maximum heat input capacity of each fuel combustion unit shall not exceed 10 MMBtu/hour and only natural gas, propane or butane may be used as fuels.

(v) The total heat input capacity of the fuel combustion units shall be equal to or less than 30 MMBtu/hour.

(vi) The capacity of any volatile organic liquid storage tank shall not exceed 19,812 gallons.

(vii) All solvents shall be stored in closed containers.

(viii) Button and lint traps shall be cleaned each working day.

(ix) All washer lint traps, button traps, access doors, and other parts of the equipment where solvent may be exposed to the atmosphere shall be kept closed at all times except when required for proper operation or maintenance.

(x) The still residue, used filtering material, lint, used solvent and all other wastes containing solvent shall be stored in sealed containers until properly disposed.

(xi) If your facility is located in a serious, severe or extreme ozone nonattainment area, then the permittee shall also comply with the additional equipment specifications and operating requirements specified in § 49.163(e).

(3) *Monitoring and testing requirements.* Each petroleum solvent dry cleaning dryer shall be inspected every 15 calendar days for evidence of leaks and all vapor or liquid leaks shall be repaired within the subsequent 15 calendar day period.

(4) *Recordkeeping requirements.* (i) The permittee shall maintain all records required to be kept by this permit by rule for at least 5 years from the date of origin, unless otherwise stated, either onsite or at a convenient location, such that they can be delivered to the reviewing authority within 24 hours of a request.

(ii) The Notification of Coverage and all documentation supporting the notification shall be maintained by the permittee for the duration of time the affected emissions unit(s) is covered under this permit by rule.

(iii) The permittee shall maintain a log of:

(A) The results of the daily leak inspections, any corrective actions taken to repair leaks, and the results of any corrective actions taken;

(B) Each type of petroleum solvent used at the facility;

(C) The date, type, and amount of solvent (in gallons) added to the solvent tank of each dry cleaning machine; and

(D) The monthly total gallons of petroleum solvent used and the resulting 12-month rolling total of solvent used. The 12-month rolling total is defined as the sum of the gallons of petroleum solvent used during the current month and the gallons of petroleum solvent used for the previous eleven (11) months.

(5) *Notification and reporting requirements*—(i) *Notification of construction or modification, and operations.* The permittee shall submit a written or electronic notice to the reviewing authority within 30 days from when the permittee begins actual construction, and within 30 days from when the permittee begins initial operations or resumes operations after modification.

(ii) *Notification of change in ownership or operator.* If the permitted source changes ownership or operator, then the new owner must submit a written or electronic notice to the

reviewing authority within 90 days before or after the change in ownership is effective. In the notice, the new permittee must provide the reviewing authority a written agreement containing a specific date for transfer of ownership, and an effective date on which the new owner assumes partial and/or full coverage and liability under this permit by rule. The submittal must identify the previous owner, and update the name, street address, mailing address, contact information, and any other information about the permitted source if it would change as a result of the change of ownership. The current owner shall ensure that the permitted source remains in compliance with the permit by rule until such transfer of ownership is effective.

(iii) *Notification of closure.* The permittee must submit a report of any permanent or indefinite closure to the reviewing authority in writing within 90 days after the cessation of all operations at the permitted source. It is not necessary to submit a report of closure for regular, seasonal closures.

(iv) *Annual reports.* The permittee shall submit an annual report on or before March 15 of each calendar year to the reviewing authority. The annual report shall cover the period from January 1 to December 31 of the previous calendar year and shall include:

(A) An evaluation of the permitted source's compliance status with the requirements in paragraph (d)(2) of this section;

(B) Summaries of the required monitoring and recordkeeping in paragraphs (d)(3) and (4) of this section; and

(C) Summaries of deviation reports submitted pursuant to paragraph (d)(5)(v) of this section.

(v) *Deviation reports.* The permittee shall promptly report to the reviewing authority any deviations as defined at 40 CFR 71.6(a)(3)(iii)(C) from permit by rule requirements including deviations attributable to upset conditions. (For the purposes of this permit by rule, *promptly* shall be defined to mean: At the time the annual report in paragraph (d)(5)(iv) of this section is submitted.) Deviation reports shall include:

(A) The identity of affected emissions unit where the deviation occurred.

(B) The nature of the deviation;

(C) The length of time of the deviation;

(D) The probable cause of the deviation; and

(E) Any corrective actions or preventive measures taken as a result of the deviation to minimize emissions from the deviation and to prevent future deviations.

(vi) *Reporting and notification address.* The permittee shall send all required reports to the reviewing authority at the mailing address specified in paragraph (f) of this section.

(vii) *Signature verifying truth, accuracy and completeness.* All reports required by this permit by rule shall be signed by a responsible official as to the truth, accuracy and completeness of the information. The report must state that, based on information and belief formed after reasonable inquiry, the statements and information are true, accurate, and complete. If the permittee discovers that any reports or notification submitted to the reviewing authority contain false, inaccurate, or incomplete information, the permittee shall notify the reviewing authority immediately and correct or amend the report as soon as practicable.

(6) *Changes to this permit by rule*—(i) *Revising, reopening, revoking and reissuing, or terminating for cause.* The permit by rule may be revised, reopened, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit revision, revocation and re-issuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit by rule condition. This provision also applies to the documents incorporated by reference.

(ii) *Terminating coverage under this permit by rule.* The reviewing authority may terminate coverage under the permit by rule, and thereby terminate that permittee's authorization to construct or modify, and that permitted source's authorization to operate under this permit by rule for cause as defined in paragraph (b) of this section. The reviewing authority may provide the permittee with notice of the intent to terminate, and delay the effective date of the termination to allow the permittee to obtain a source-specific permit.

(iii) *Permit becomes invalid.* Authority to construct and operate under this permit by rule becomes invalid if the permittee does not commence construction within 18 months after the effective date of the Request for Coverage under the permit by rule, if the permittee discontinues construction for a period of 18 months or more, or if the permittee does not complete construction within a reasonable time. The reviewing authority may extend the 18-month period upon a satisfactory showing that an extension is justified according to 40 CFR 49.156(e)(8).

(e) *Petroleum dry cleaning facilities in certain nonattainment areas.* For facilities located in serious, severe, or extreme ozone nonattainment areas, the permittee shall operate and maintain the solvent dry cleaning system in accordance with the requirements specified below and in accordance with the manufacturer's recommendations:

(1) *General specifications.* (i) All parts of the dry cleaning system where solvent may be exposed to the atmosphere or workroom shall be kept closed at all times except when access is required for proper operation and maintenance.

(ii) Wastewater evaporators shall be operated to ensure that no liquid solvent or visible emulsion is allowed to vaporize to the atmosphere.

(2) *Additional specification for closed-loop machines.* (i) A *closed-loop machine* means dry cleaning equipment in which washing, extraction, and drying is performed within the same single affected emissions unit and which re-circulates and recovers the solvent-laden vapor.

(ii) A closed-loop machine shall not exhaust to the atmosphere or workroom during operation except when the vacuum pump exhausts to maintain a continuous vacuum.

(iii) For any closed-loop machine that is not equipped with a locking mechanism, the operator shall not open the door of a closed-loop machine prior to completion of the drying cycle.

(iv) For any closed-loop machine that is equipped with a locking mechanism, the operator shall not inactivate the locking mechanism and open the door of a closed-loop machine prior to completion of the drying cycle.

(3) *Leak check and repair requirements.* (i) No less frequently than monthly, the owner or operator shall inspect the dry cleaning system for liquid and vapor leaks, including, but not limited to, the following:

(A) Hose connections, unions, couplings, valves, and flanges;

(B) Machine door gasket and seating of the machine cylinder;

(C) Filter head gasket and seating;

(D) Pumps;

(E) Base tanks and storage containers;

(F) Water separators;

(G) Filter sludge recovery;

(H) Seals and gaskets of distillation unit(s);

(I) Diverter valves;

(J) Saturated lint from lint trap basket;

(K) Button trap lid;

(L) Cartridge or other types of filters;

(M) Seals, gaskets and the diverter valve of the refrigerated condenser;

(N) Exhaust stream ducts;

(O) Lint trap ducts; and

(P) Gaskets and ducts of the carbon adsorber.

(ii) To inspect for a vapor leak, the operator shall use at least one of the following techniques:

(A) Soap bubble technique in accordance with the procedures in EPA Method 21, section 4.3.3—Alternative Screening Procedure;

(B) A non-halogenated hydrocarbon detector;

(C) A portable hydrocarbon analyzer; or

(D) An alternative method approved by the reviewing authority.

(iii) To inspect for a liquid leak, the operator shall visually inspect the equipment for liquid leaking in a visible mist or at the rate of more than one drop every 3 minutes.

(iv) Any liquid leak or vapor leak that has been detected by the operator shall be repaired within 3 working days of detection. If repair parts are not available at the facility, the parts shall be ordered within 2 working days of detecting such a leak and the operator shall provide written notification to the reviewing authority that explains the reason(s) for delaying the leak repair. Such repair parts shall be installed within 5 working days after receipt. A facility with a leak that has not been repaired by the end of the 7th working day after detection shall not operate the dry cleaning equipment, until the leak is repaired.

(f) *List of reviewing authorities and areas of coverage.*

TABLE 1—LIST OF REVIEWING AUTHORITIES AND AREAS OF COVERAGE

| EPA region | Address for notification of coverage | Address for all other notifications and reports | Area covered | Phone number |
|---|---|---|---|---|
| Region I | EPA New England, 5 Post Office Square, Suite 100, Mail Code OEP05–2, Boston, MA 02109–3912. | EPA New England, 5 Post Office Square, Suite 100, Mail Code OES04–2, Boston, MA 02109–3912. | Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. | 888–372–7341 617–918–1111 |
| Region II | Chief, Air Programs Branch, Clean Air and Sustainability Division, EPA Region 2, 290 Broadway, 25th Floor, New York, NY 10007–1866. | Chief, Air Compliance Branch, Division of Enforcement and Compliance Assistance, EPA Region 2, 290 Broadway, 21st Floor, New York, NY 10007–1866. | New Jersey, New York, Puerto Rico, and Virgin Islands. | 877–251–4575 |
| Region III | Office of Permits and Air Toxics, 3AP10, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. | Office of Air Enforcement and Compliance Assurance, 3AP20, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. | Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. | 800–438–2474 215–814–5000 |
| Region IV | Chief, Air Permits Section, EPA Region 4 APTMD, 61 Forsyth Street, Atlanta, GA 30303. | Chief, Air & EPCRA Enforcement Branch, EPA Region 4 APTMD, 61 Forsyth Street SW., Atlanta, GA 30303. | Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. | 800–241–1754 404–562–9000 |
| Region V | Air Permits Section, Air Programs Branch (AR–18J), EPA Region 5, 77 West Jackson Blvd, Chicago, IL 60604. | Air Enforcement and Compliance Assurance Branch (AE–17J), Air and Radiation Division, EPA Region 5, 77 West Jackson Blvd, Chicago, IL 60604. | Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. | 800–621–8431 312–353–2000 |
| Region VI | Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue (6PD–R), Dallas, TX 75202. | Compliance and Enforcement Correspondence:, Compliance Assurance and Enforcement Division, EPA Region 6, 1445 Ross Avenue (6EN), Dallas, TX 75202. | Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. | 800–887–6063 214–665–2760 |
| Region VII | Chief, Air Permitting & Compliance Branch, EPA Region 7, 11201 Renner Blvd, Lenexa, KS 66219. | Chief, Air Permitting & Compliance Branch, EPA Region 7, 11201 Renner Blvd, Lenexa, KS 66219. | Iowa, Kansas, Missouri, and Nebraska. | 800–223–0425 913–551–7003 |
| Region VIII | U.S. Environmental Protection Agency, Region 8, Office of Partnerships and Regulatory Assistance, Tribal Air Permitting Program, 8P–AR, 1595 Wynkoop Street, Denver, CO 80202. | U.S. Environmental Protection Agency, Region 8, Office of Enforcement, Compliance & Environmental Justice, Air Toxics and Technical Enforcement Program, 8ENF–AT, 1595 Wynkoop Street, Denver, CO 80202. | Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. | 800–227–8917 303–312–6312 |
| Region IX | Chief, Permits Office (Air-3), Air Division, EPA Region 9, 75 Hawthorne St, San Francisco, CA 94105. | Enforcement Division Director, Attn: Air & TRI Section (ENF–2–1), EPA Region 9, 75 Hawthorne St, San Francisco, CA 94105. | American Samoa, Arizona, California, Guam, Hawaii, Navajo Nation Nevada, and Northern Mariana Islands. | 866–EPA–9378 415–947–8000 |
| Region X | Tribal Air Permits Coordinator, U.S. EPA, Region 10, AWT–150, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. | Tribal Air Permits Coordinator, U.S. EPA, Region 10, AWT–150, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. | Alaska, Idaho, Oregon, and Washington. | 800–424–4372 206–553–1200 |

■ 6. Section 49.164 is added to read as follows:

**§ 49.164 Air quality permit by rule for new or modified true minor source gasoline dispensing facilities in Indian country.**

(a) *Abbreviations and acronyms:*

AST Aboveground Storage Tank
CAA or the Act Federal Clean Air Act
CFR Code of Federal Regulations

EPA United States Environmental Protection Agency
GDF Gasoline Dispensing Facility
NAAQS National Ambient Air Quality Standards
NSR New Source Review
ppm parts per million
PSD Prevention of Significant Deterioration
PV Pressure/Vacuum
VOC Volatile Organic Compounds

(b) *Definitions for the purposes of this permit by rule.* (1) *Cause* means with respect to the reviewing authority's ability to terminate a permitted source's coverage under a permit that:

(i) The permittee is not in compliance with the provisions of this permit by rule;

(ii) The reviewing authority determines that the emissions resulting from the construction or modification of the permitted source significantly contribute to NAAQS violations, which are not adequately addressed by the requirements in this permit by rule;

(iii) The reviewing authority has reasonable cause to believe that the permittee obtained coverage under the permit by rule by fraud or misrepresentation; or

(iv) The permittee failed to disclose a material fact required by the Notification of Coverage or the requirements applicable to the permitted source of which the applicant had or should have had knowledge at the time the permittee submitted the Notification of Coverage.

(2) *Construction* means any physical change or change in the method of operation including fabrication, erection, installation, demolition, or modification of an affected emissions unit that would result in a change of emissions.

(3) *Dual-point vapor balance system* means a type of vapor balance system in which the storage tank is equipped with an entry port for a gasoline fill pipe and a separate exit port for a vapor connection.

(4) *Emergency engine* means any stationary reciprocating internal combustion engine that meets all of the criteria in paragraphs (b)(4)(i) through (iii) of this section. All emergency engines must comply with the requirements specified in 40 CFR 63.6640(f) in order to be considered emergency engines. If the engine does not comply with the requirements specified, then it is not considered to be an emergency engine.

(i) The engine is operated to provide electrical power or mechanical work during an emergency situation. Examples include engines used to produce power for critical networks or equipment (including power supplied to portions of a facility) when electric power from the local utility (or the normal power source, if the facility runs on its own power production) is interrupted, or an engine used to pump water in the case of fire or flood, etc.

(ii) The engine is operated under limited circumstances for situations not included in paragraph (b)(4)(i) of this section, as specified in 40 CFR 63.6640(f).

(iii) The engine operates as part of a financial arrangement with another entity in situations not included in paragraph (b)(4)(i) of this definition only as allowed in 40 CFR 63.6640(f).

(5) *Notification of Coverage* means the permit notification that contains all the information required in the standard notification form for this permit by rule.

(6) *Permittee* means the owner or operator of a permitted source.

(7) *Permitted source* means each gasoline dispensing facility for which a permitted source submits a complete Notification of Coverage.

(8) *Responsible official* means one of the following:

(i) For a corporation: a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is directly responsible for the overall operation of the permitted source;

(ii) For a partnership or sole proprietorship: a general partner or the proprietor, respectively; or

(iii) For a public agency: Either a principal executive officer or ranking elected official, such as a chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency.

(9) *Submerged filling* means the filling of a gasoline storage tank through a submerged fill pipe whose discharge is no more than 6 inches from the bottom of the tank. Bottom filling of gasoline storage tanks is covered under this submerged filling definition.

(10) *Ullage* means the volume of a container not occupied by liquid. For example, the ullage of a tank designed primarily for containing liquid is the volume of the tank minus the volume of the liquid it contains.

(11) *Vapor balance system* means a combination of pipes and hoses that create a closed system between the vapor spaces of an unloading gasoline cargo tank and a receiving storage tank such that vapors displaced from the storage tank are transferred to the gasoline cargo tank being unloaded.

(12) *Vapor tight* means equipment that allows no loss of vapors. Compliance with vapor-tight requirements can be determined by checking to ensure that the concentration at a potential leak source is not equal to or greater than 100 percent of the lower explosive limit when measured with a combustible gas detector, calibrated with propane, at a distance of 1 inch from the potential leak source.

(c) *Information about this permit by rule*—(1) *Applicability.* Pursuant to the provisions of the CAA, subchapter I, part D and 40 CFR part 49, subpart C, this permit authorizes the construction or modification and the operation of each stationary gasoline dispensing facility (GDF) for which a reviewing authority receives a completed Notification of Coverage (permitted source).

(2) *Eligibility.* To be eligible for coverage under this permit by rule, the permitted source must qualify as a true minor source as defined in 40 CFR 49.152 and satisfied the requirements in 40 CFR 49.156(f)(6)(iii). In addition, coverage under this Permit by Rule is not available in areas located within the geographic boundaries of California.

(3) *Notification of Coverage.* Requirements for submitting a Notification of Coverage are contained in paragraph (d)(1) of this permit by rule. The information contained in each permitted source's Notification of Coverage is hereby enforceable under this permit by rule.

(4) *Termination.* Paragraph (d)(6) of this permit by rule addresses a reviewing authority's ability to revise, revoke and reissue, or terminate coverage under this permit by rule. It also addresses the reviewing authority's ability to terminate an individual permitted source's coverage under this permit by rule.

(5) *Definitions.* The terms used herein shall have the meaning as defined in 40 CFR 49.152, unless otherwise defined in paragraph (b) of this permit by rule. If a term is not defined, it shall be interpreted in accordance with normal business use.

(d) *Permit by rule terms and conditions.* The following applies to each permittee and permitted source with respect to only the affected emissions units and any associated air pollution control technologies in that permitted source's Notification of Coverage.

(1) *General provisions*—(i) *Obtaining coverage under this permit by rule.* To obtain coverage under this permit by rule, an applicant must submit a completed Notification of Coverage to

the appropriate reviewing authority for the area in which the permitted source is or will be located (the Notification of Coverage Form can be found at: *http://www.epa.gov/air/tribal/tribalnsr.html*). Table 1 of paragraph (f) contains a list of reviewing authorities and their area of coverage. You must also submit a copy of the Notification of Coverage to the Indian governing body for any area in which the permitted source will operate. Coverage under this permit by rule is not available in areas within the geographical boundaries of California.

(ii) *Construction and operation.* The permittee shall construct or modify and shall operate the affected emissions units and any associated air pollution control technologies in compliance with this permit by rule and all other applicable federal air quality regulations; and in a manner consistent with representations made by the permittee in the Notification of Coverage.

(iii) *Locations.* This permit by rule only authorizes the permittee to construct or modify and to operate the permitted source in the location(s) listed in the Notification of Coverage for that permitted source.

(iv) *Liability.* This permit by rule does not release the permittee from any liability for compliance with other applicable federal and tribal environmental laws and regulations, including the CAA.

(v) *Severability.* The provisions of this permit by rule are severable. If any portion of this permit by rule is held invalid, the remaining terms and conditions of this permit by rule shall remain valid and in force.

(vi) *Compliance.* The permittee must comply with all provisions of this permit by rule, including emission limitations that apply to the affected emissions units at the permitted source. Noncompliance with any permit provision is a violation of this permit by rule and may constitute a violation of CAA; is grounds for an enforcement action; and is grounds for the reviewing authority to revoke and terminate the permitted source's coverage under this permit by rule.

(vii) *National Ambient Air Quality Standards (NAAQS)/Prevention of Significant Deterioration (PSD) Protection.* The permitted source must not cause or contribute to a NAAQS violation or, in an attainment area, must not cause or contribute to a PSD increment violation.

(viii) *Unavailable defense.* It is not a defense for the permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the provisions of this permit by rule.

(ix) *Property rights.* This permit by rule does not convey any property rights of any sort or any exclusive privilege.

(x) *Information requests.* You, as the permittee, shall furnish to the reviewing authority, within 30 days unless another timeframe is specified by the EPA, any information that the reviewing authority may request in writing to determine whether cause exists for revising, revoking and reissuing, or terminating coverage under the permit by rule or to determine compliance with the permit by rule. For any such information claimed to be confidential, the permittee must submit a claim of confidentiality in accordance with 40 CFR part 2 subpart B.

(xi) *Inspection and entry.* Upon presentation of proper credentials, the permittee must allow a representative of the reviewing authority to:

(A) Enter upon the premises where a permitted source is located or emissions-related activity is conducted or where records are required to be kept under the conditions of the permit by rule;

(B) Have access to and copy, at reasonable times, any records that are required to be kept under the conditions of the permit by rule;

(C) Inspect, during normal business hours or while the permitted source is in operation, any facilities, equipment (including monitoring and air pollution control equipment), practices or operations regulated or required under the permit by rule;

(D) Sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with the permit by rule or other applicable requirements; and

(E) Record any inspection by use of written, electronic, magnetic and photographic media.

(xii) *Posting of coverage.* The most current Notification of Coverage for the permitted source, must be posted prominently at the facility, and each affected emissions unit and any associated air pollution control technology must be labeled with the identification number listed in the Notification of Coverage for that permitted source.

(xiii) *Duty to obtain source-specific permit.* If the reviewing authority intends to terminate a permitted source's coverage under this permit by rule for cause as provided in § 49.164(d)(6), then the permittee shall apply for and obtain a source-specific as required by the reviewing authority.

(xiv) *Credible evidence.* For the purpose of establishing whether the permittee violated or is in violation of any requirement of this permit by rule, nothing shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether a permitted source would have been in compliance with applicable requirements if the permittee had performed the appropriate performance or compliance test or procedure.

(2) *Emission limitations and standards.* (i) The permittee shall install, maintain, and operate each affected emissions unit, including any associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions of NSR regulated pollutants and considering the manufacturer's recommended operating procedures at all times, including periods of startup, shutdown, maintenance and malfunction. The reviewing authority will determine whether the permittee is using acceptable operating and maintenance procedures based on information available to the reviewing authority which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection of the permitted source.

(ii) GDFs located in an ozone attainment, unclassifiable or attainment/unclassifiable area or a marginal or moderate ozone nonattainment area shall limit throughput of gasoline to less than 25,000,000 gallons per year based on a 12-month rolling total.

(iii) GDFs located in a serious, severe or extreme ozone nonattainment area shall limit throughput of gasoline to less than 8,000,000 gallons per year based on a 12-month rolling total.

(iv) You must ensure gasoline is handled in a manner that will minimize vapor releases to the atmosphere. The measures to be taken include:

(A) Minimizing gasoline spills;

(B) Cleaning up spills as expeditiously as practicable. The spill bucket shall be free from standing liquid and debris;

(C) Covering all open gasoline containers and all gasoline storage tank fill-pipes with a gasketed seal when not in use (all portable gasoline containers that meet the requirements of 40 CFR part 59, subpart F meet this requirement);

(D) Minimizing gasoline sent to open waste collection systems that collect and transport gasoline to reclamation and recycling devices, such as oil/water separators; and

(E) To the extent practicable, any other actions necessary to minimize vapor releases to the atmosphere.

(v) Except as specified in paragraph (d)(2)(v)(B) of this section, you must only load gasoline into storage tanks at your facility by utilizing submerged filling, and as specified in this condition. The applicable distances shall be measured from the point in the opening of the submerged fill pipe that is the greatest distance from the bottom of the storage tank.

(A) Submerged fill pipes must be no more than 6 inches from the bottom of the tank.

(B) Submerged fill pipes not meeting the specifications paragraph (d)(2)(v)(A) of this section are allowed if the owner or operator can demonstrate that the liquid level in the tank is always above the entire opening of the fill pipe. Documentation providing such demonstration must be made available onsite for inspection by the reviewing authority.

(vi) Except as provided in paragraph (d)(2)(viii) of this section, each new or modified gasoline storage tank constructed must be equipped with a Stage I dual-point vapor balance system.

(vii) Except as provided in paragraph (d)(2)(viii) of this section, each Stage I dual-point vapor balance system on your gasoline storage tank must meet the design criteria and management practices in paragraph (e) of this section, as applicable.

(viii) The affected emissions units listed below are not required to comply with the control requirements in paragraphs (d)(2)(vi) and (vii) of this section, but must comply with the requirements in paragraph (d)(2)(v) of this section.

(A) Gasoline storage tanks with a capacity of less than 250 gallons.

(B) Gasoline storage tanks with a capacity of less than 2,000 gallons.

(C) Gasoline storage tanks equipped with floating roofs, or the equivalent.

(ix) Cargo tanks unloading at GDFs must not unload gasoline into a storage tank at a GDF unless the following management practices are met:

(A) All hoses in the vapor balance system are properly connected;

(B) The adapters or couplers that attach to the vapor line on the storage tank have closures that seal upon disconnect;

(C) All vapor return hoses, couplers, and adapters used in gasoline delivery are vapor-tight;

(D) All tank truck vapor return equipment is compatible in size and forms a vapor-tight connection with the vapor balance equipment on the GDF storage tank;

(E) All hatches on the tank truck are closed and securely fastened; and

(F) The filling of storage tanks at GDF shall be limited to unloading from vapor-tight gasoline cargo tanks.

(x) Each emergency engine shall:

(A) Be equipped with a non-resettable hour meter;

(B) If using fuel oil, use diesel or biodiesel containing no more than 15 ppm (0.0015 percent) sulfur;

(C) Meet the following certification requirement for compression ignition emergency engines: for model year 2006 and later engines, the engine shall be certified to the standards in 40 CFR part 89.

(D) Meet the following certification requirements for spark ignition emergency engines manufactured on or after January 1, 2009:

(1) Engines greater than 50 hp and less than 130 hp shall be certified to the Phase I standards in 40 CFR 90.103; and

(2) Engines greater than or equal to 130 hp shall be certified to the standards in 40 CFR 1048.

(E) If not required to be certified to the standards in paragraph (d)(2)(x)(C) or (D) of this section:

(*1*) Follow the manufacturer's emission-related operation and maintenance instructions or develop your own maintenance plan which must provide to the extent practicable for the maintenance and operation of the engine in a manner consistent with good air pollution control practice for minimizing emissions;

(*2*) Change oil and filter and inspect every hose and belt every 500 hours of operation or annually, whichever comes first; and

(*3*) Inspect air cleaner or spark plugs, as applicable, every 1,000 hours of operation, or annually, whichever comes first.

(3) *Monitoring and testing requirements.* (i) For each vapor balance system, the permittee shall perform an initial performance test as prescribed in paragraph (e) of this section and every 3 years thereafter. The performance test shall be conducted within 60 days after achieving the maximum production rate at which the permitted source will operate the affected vapor balance system, but not later than 180 days after the first day of operation after the reviewing authority receives the completed Notification of Coverage.

(ii) The permittee shall monitor monthly gasoline throughput in gallons.

(iii) The permittee shall perform weekly inspections of the vapor control recovery system(s), all pumps, compressors, pipes, hoses, mechanical seals, or other equipment storing, handling, conveying, or controlling VOCs. For sources located in extreme ozone nonattainment areas, these equipment inspections shall be performed daily. The inspections shall be used to determine whether all equipment is in good working order according to any available manufacturer's recommendations and good engineering practices.

(4) *Recordkeeping requirements.* (i) The permittee shall maintain all records required to be kept onsite by this permit by rule for at least 5 years from the date of origin, unless otherwise stated.

(ii) The Notification of Coverage and all documentation supporting that application shall be maintained by the permittee for the duration of time the affected emissions unit(s) is covered under this permit by rule.

(iii) The permittee shall maintain records of each inspection required by paragraph (d)(3)(iii) of this section. The records shall include a log of:

(A) Identification of the devices inspected;

(B) The date of the inspection;

(C) The results of each inspection;

(D) Any corrective actions taken as a result of the inspection; and

(E) The results of any corrective actions taken.

(iv) For each emergency engine, the permittee shall maintain a log of all maintenance activities conducted and a log of the hours of operation including the date, time, duration, and reason for use.

(v) The permittee shall maintain records on a monthly basis of the fuel throughput and the 12-month rolling total. The 12-month rolling total is defined as the sum of the fuel throughput during the current month and the fuel throughput for the previous 11 months.

(vi) The results of each performance test conducted pursuant to § 49.164(d)(3)(i) shall be recorded. At a minimum, the permittee shall maintain records of:

(A) The date of each test;

(B) Each test plan;

(C) Any documentation required to approve an alternate test method;

(D) Test conditions;

(E) The results of each test; and

(F) The name of the company or entity conducting the analysis.

(5) *Notification and reporting requirements*—(i) *Notification of construction or modification, and operations.* The permittee shall submit a written or electronic notice to the reviewing authority within 30 days from when the permittee begins actual construction, and within 30 days from when the permittee begins initial operations or resumes operation after a modification.

(ii) *Notification of change in ownership or operator.* If the permitted source changes ownership or operator, then the new owner must submit a written or electronic notice to the reviewing authority within 90 days before or after the change in ownership is effective. In the notice, the new permittee must provide the reviewing authority a written agreement containing a specific date for transfer of ownership, and an effective date on which the new owner assumes partial and/or full coverage and liability under this permit by rule. The submittal must identify the previous owner, and update the name, street address, mailing address, contact information, and any other information about the permitted source if it would change as a result of the change of ownership. The current owner shall ensure that the permitted source remains in compliance with the permit by rule until any such transfer of ownership is effective.

(iii) *Notification of closure.* The permittee must submit a report of any permanent or indefinite closure to the reviewing authority in writing within 90 days after the cessation of all operations at the permitted source. The notification must identify the owner, the current location, and the last operating location of the permitted source. It is not necessary to submit a report of closure for regular, seasonal closures.

(iv) *Annual reports.* The permittee shall submit an annual report on or before March 15 of each calendar year to the reviewing authority. The annual report shall cover the period from January 1 to December 31 of the previous calendar year and shall include:

(A) An evaluation of the permitted source's compliance status with the emission limitations and standards in paragraph (d)(2) of this section;

(B) Summaries of the required monitoring and recordkeeping in paragraphs (d)(3) and (4) of this section; and

(C) Summaries of deviation reports submitted pursuant to paragraph (d)(5)(v) of this section.

(v) *Deviation reports.* The permittee shall promptly report to the reviewing authority any deviations as defined at 40 CFR 71.6(a)(3)(iii)(C) from the permit by rule requirements including deviations attributable to upset conditions. (For the purposes of this permit by rule, promptly shall be defined to mean: at the time the annual report in paragraph (d)(5)(iv) of this section is submitted.) Deviation reports shall include:

(A) The identity of affected emissions unit where the deviation occurred;

(B) The nature of the deviation;

(C) The length of time of the deviation;

(D) The probable cause of the deviation; and

(E) Any corrective actions or preventive measures taken as a result of the deviation to minimize emissions from the deviation and to prevent future deviations.

(vi) *Performance test reports.* The permittee shall submit a test report to the reviewing authority within 45 days after the completion of any required performance test. At a minimum, the test report shall include:

(A) A description of the affected emissions unit and sampling location(s);

(B) The time and date of each test;

(C) A summary of test results, reported in units consistent with the applicable standard;

(D) A description of the test methods and quality assurance procedures used;

(E) A summary of any deviations from the proposed test plan and justification for why the deviation(s) was necessary;

(F) Operating parameters of the affected emissions unit and control equipment during each test run;

(G) Sample calculations of equations used to determine test results in the appropriate units; and

(H) The name of the company or entity performing the analysis.

(vii) *Reporting and notification address.*The permittee shall send all required reports to the reviewing authority at the mailing address specified in paragraph (f) of this section.

(viii) *Signature verifying truth, accuracy and completeness.* All reports required by this permit by rule shall be signed by a responsible official as to the truth, accuracy and completeness of the information. The report must state that, based on information and belief formed after reasonable inquiry, the statements and information are true, accurate, and complete. If the permittee discovers that any reports or notification submitted to the reviewing authority contain false, inaccurate, or incomplete information, the permittee shall notify the reviewing authority immediately and correct or amend the report as soon as practicable.

(6) *Changes to this permit by rule*—

(i) *Revising, reopening, revoking and reissuing, or terminating for cause.* The permit by rule may be revised, reopened, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit revision, revocation and re-issuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit by rule condition. This provision also applies to the documents incorporated by reference.

(ii) *Terminating coverage under this permit by rule.* The reviewing authority may terminate coverage under this permit by rule, and thereby terminate that permittee's authorization to construct or modify, and that permitted source's authorization to operate under this permit by rule for cause as defined in paragraph (b) of this section. The reviewing authority may provide the permittee with notice of the intent to terminate, and delay the effective date of the termination to allow the permittee to obtain a source specific permit as required by the reviewing authority.

(iii) *Permit becomes invalid.* Authority to construct and operate under this permit by rule becomes invalid if the permittee does not commence construction within 18 months after the Notification of Coverage is received by the reviewing authority, if the permittee discontinues construction for a period of 18 months or more, or if the permittee does not complete construction within a reasonable time. The reviewing authority may extend the 18-month period upon a satisfactory showing that an extension is justified according to 40 CFR 49.156(e)(8).

(e) *Vapor balance system design criteria, management practices, and performance testing.* (1) Design criteria and management practices for each vapor balance system:

(i) All vapor connections and lines on the storage tank(s) shall be equipped with closures that seal upon disconnect.

(ii) The vapor line from the gasoline storage tank to the gasoline cargo tank shall be vapor-tight.

(iii) The vapor balance system shall be designed such that the pressure in the tank truck does not exceed 18 inches water pressure or 5.9 inches water vacuum during product transfer.

(iv) The vapor recovery and product adaptors, and the method of connection with the delivery elbow, shall be designed so as to prevent the over-tightening or loosening of fittings during normal delivery operations.

(v) If a gauge well separate from the fill tube is used, it shall be provided with a submerged drop tube that extends no more than 6 inches from the bottom of the storage tank.

(vi) Liquid fill connections for all systems shall be equipped with vapor-tight caps.

(vii) Pressure/vacuum (PV) vent valves shall be installed on the storage tank vent pipes. The pressure specifications for PV vent valves shall be: a positive pressure setting of 2.5 to 6.0 inches of water and a negative

pressure setting of 6.0 to 10.0 inches of water. The total leak rate of all PV vent valves at an affected facility, including connections, shall not exceed 0.17 cubic foot per hour at a pressure of 2.0 inches of water and 0.63 cubic foot per hour at a vacuum of 4 inches of water.

(viii) The vapor balance system shall be capable of meeting the static pressure performance requirement of the following equation: $Pf = 2e^{-500.887/v}$, where: Pf = minimum allowable final pressure, inches of water, v = total ullage affected by the test, gallons, e = dimensionless constant equal to approximately 2.718, 2 = the initial pressure, inches water.

(ix) For aboveground storage tanks (ASTs) with a capacity greater than 250 gallons and located at a GDF in a serious, severe, or extreme ozone nonattainment area the permittee shall also:

(A) Limit standing loss emissions to less than or equal to 0.57 lbs VOC per 1,000 gallons ullage per day (lbs/1,000 gallons/day), for newly installed tanks.

(B) Limit standing loss emissions to less than or equal to 2.26 lbs VOC per 1,000 gallons ullage per day (lbs/1,000 gallons/day), for modified or reconstructed tanks.

(2) Vapor balance system performance testing:

(i) The permittee shall conduct performance testing to demonstrate compliance with the leak rate and cracking pressure requirements, specified in paragraph (e)(1)(vii) of this section, for pressure-vacuum vent valves installed on your gasoline storage tanks as follows:

(A) According to a test plan submitted at least 30 days in advance of the test date to the reviewing authority; and

(B) Using California Air Resources Board Vapor Recovery Test Procedure TP–201.1E,—Leak Rate and Cracking Pressure of Pressure/Vacuum Vent Valves, adopted October 8, 2003 (see 40 CFR 63.14).

(ii) The permittee shall conduct performance testing to demonstrate compliance with the static pressure performance requirement, specified in paragraph (e)(1)(viii) of this section, for each vapor balance system by conducting a static pressure test on each gasoline storage tank as follows:

(A) According to a test plan submitted at least 30 days in advance of the test date to the reviewing authority;

(B) Using California Air Resources Board Vapor Recovery Test Procedure TP–201.3,—Determination of 2-Inch WC Static Pressure Performance of Vapor Recovery Systems of Dispensing Facilities, adopted April 12, 1996, and amended March 17, 1999 (see 40 CFR 63.14) or Bay Area Air Quality Management District Source Test Procedure ST–30—Static Pressure Integrity Test—Underground Storage Tanks, adopted November 30, 1983, and amended December 21, 1994 (see 40 CFR 63.14); and

(iii) For ASTs subject to § 49.164(e)(1)(ix), the ASTs shall be California Air Resources Board certified AST for Standing Loss Control per Vapor Recovery Test Procedures TP–206.1 or TP–206.2.

(f) *List of reviewing authorities, and areas of coverage.*

TABLE 1—LIST OF REVIEWING AUTHORITIES, AND AREAS OF COVERAGE

| EPA region | Address for notification of coverage | Address for all other notification and reports | Area covered | Phone number |
|---|---|---|---|---|
| Region I | EPA New England, 5 Post Office Square, Suite 100, Mail Code OEP05–2, Boston, MA 02109–3912. | EPA New England, 5 Post Office Square, Suite 100, Mail Code OES04–2, Boston, MA 02109–3912. | Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. | 888–372–7341<br>617–918–1111 |
| Region II | Chief, Air Programs Branch, Clean Air and Sustainability Division, EPA Region 2, 290 Broadway, 25th Floor, New York, NY 10007–1866. | Chief, Air Compliance Branch, Division of Enforcement and Compliance Assistance, EPA Region 2, 290 Broadway, 21st Floor, New York, NY 10007–1866. | New Jersey, New York, Puerto Rico, and Virgin Islands. | 877–251–4575 |
| Region III | Office of Permits and Air Toxics, 3AP10, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. | Office of Air Enforcement and Compliance Assurance, 3AP20, EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103. | Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia. | 800–438–2474<br>215–814–5000 |
| Region IV | Chief, Air Permits Section, EPA Region 4 APTMD, 61 Forsyth Street, Atlanta, GA 30303. | Chief, Air & EPCRA Enforcement Branch, EPA Region 4 APTMD, 61 Forsyth Street, SW, Atlanta, GA 30303. | Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. | 800–241–1754<br>404–562–9000 |
| Region V | Air Permits Section, Air Programs Branch (AR–18J), EPA Region 5, 77 West Jackson Blvd, Chicago, IL 60604. | Air Enforcement and Compliance Assurance Branch (AE–17J), Air and Radiation Division, EPA Region 5, 77 West Jackson Blvd, Chicago, IL 60604. | Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. | 800–621–8431<br>312–353–2000 |
| Region VI | Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue (6PD–R), Dallas, TX 75202. | Compliance and Enforcement Correspondence: Compliance Assurance and Enforcement Division, EPA Region 6, 1445 Ross Avenue (6EN), Dallas, TX 75202. | Arkansas, Louisiana, New Mexico, Oklahoma, and Texas. | 800–887–6063<br>214–665–2760 |
| Region VII | Chief, Air Permitting & Compliance Branch, EPA Region 7, 11201 Renner Blvd, Lenexa, KS 66219. | Chief, Air Permitting & Compliance Branch, EPA Region 7, 11201 Renner Blvd, Lenexa, KS 66219. | Iowa, Kansas, Missouri, and Nebraska. | 800–223–0425<br>913–551–7003 |

TABLE 1—LIST OF REVIEWING AUTHORITIES, AND AREAS OF COVERAGE—Continued

| EPA region | Address for notification of coverage | Address for all other notification and reports | Area covered | Phone number |
|---|---|---|---|---|
| Region VIII ..... | U.S. Environmental Protection Agency, Region 8, Office of Partnerships and Regulatory Assistance, Tribal Air Permitting Program, 8P–AR, 1595 Wynkoop Street, Denver, CO 80202. | U.S. Environmental Protection Agency, Region 8, Office of Enforcement, Compliance & Environmental Justice, Air Toxics and Technical Enforcement Program, 8ENF–AT, 1595 Wynkoop Street, Denver, CO 80202. | Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. | 800–227–8917<br>303–312–6312 |
| Region IX ..... | Chief, Permits Office (Air-3), Air Division, EPA Region 9, 75 Hawthorne St, San Francisco, CA 94105. | Enforcement Division Director, Attn: Air & TRI Section (ENF–2–1), EPA Region 9, 75 Hawthorne St, San Francisco, CA 94105. | American Samoa, Arizona, California, Guam, Hawaii, Navajo Nation Nevada, and Northern Mariana Islands. | 866–EPA–9378<br>415–947–8000 |
| Region X ..... | Tribal Air Permits Coordinator, U.S. EPA, Region 10, AWT–150, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. | Tribal Air Permits Coordinator, U.S. EPA, Region 10, AWT–150, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. | Alaska, Idaho, Oregon, and Washington. | 800–424–4372<br>206–553–1200 |

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Part IV

## Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 648

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Final Rule and Interim Final Rule

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 648**

**[Docket No. 150105004–5355–01]**

**RIN 0648–BE75**

# Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Groundfish Fishery; Framework Adjustment 53

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

**ACTION:** Final rule; request for comments.

**SUMMARY:** This final rule approves and implements Framework Adjustment 53 to the Northeast Multispecies Fishery Management Plan. This rule sets fishing years 2015–2017 catch limits for several groundfish stocks, modifies management measures for Gulf of Maine cod, and adopts other measures to improve the management of the groundfish fishery. This action is necessary to respond to updated scientific information and achieve the goals and objectives of the fishery management plan. The final measures are intended to prevent overfishing, rebuild overfished stocks, achieve optimum yield, and ensure that management measures are based on the best scientific information available.

**DATES:** Effective May 1, 2015. Comments on the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule must be received by June 30, 2015.

**ADDRESSES:** Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted by either of the following methods:

• *Electronic Submission:* Submit all electronic public comments via email to *OIRA_Submission@omb.eop.gov*.

• *Mail:* Submit written comments to John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on Groundfish Daily Catch Reporting.''

Copies of Framework Adjustment 53, including the Environmental Assessment, the Regulatory Impact Review, and the Iinal Regulatory Flexibility Act analysis prepared by the New England Fishery Management Council and NMFS in support of this action are available from John K. Bullard, Regional Administrator, NMFS Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. The supporting documents are also accessible via the Internet at: *http://www.nefmc.org/management-plans/northeast-multispecies* or *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies*.

**FOR FURTHER INFORMATION CONTACT:** Sarah Heil, Fishery Policy Analyst, phone: 978–281–9257; email: *Sarah.Heil@noaa.gov.*

**SUPPLEMENTARY INFORMATION:**

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11. Regulatory Corrections Under Regional Administrator Authority

## 1. Summary of Approved Measures

This final rule approves and implements measures in Framework Adjustment 53 to the Northeast Multispecies Fishery Management Plan (FMP), and removes all measures that we previously implemented in the 2014 interim action for Gulf of Maine (GOM) cod. The New England Fishery Management Council developed Framework 53 primarily in response to new stock assessments that were conducted in 2014 for a number of groundfish stocks. The new measures implemented by this final rule include:

• Revised status determination criteria for several groundfish stocks;

• Fishing year 2015 shared U.S./Canada quotas for transboundary Georges Bank (GB) stocks;

• Fishing years 2015–2017 catch limits for several groundfish stocks;

• GOM cod protection closures and possession restrictions;

• A mechanism to set default catch limits in the event a future management action is delayed; and

• A provision that allows groundfish sectors to carry over unused quota in response to a recent court ruling.

This action also implements a number of other measures that are not part of Framework 53, but that were considered under our authority specified in the FMP. We are including these measures in conjunction with the Framework 53 approved measures for expediency purposes. The additional measures implemented in this rule are listed below.

• *Management measures for the common pool fishery*—this action implements initial fishing year 2015 trip limits for the common pool fishery. We have the authority to set management measures for the common pool fishery that will help ensure that the fishery achieves, but does not exceed, its catch limits.

• *Accountability measure (AM) for northern windowpane flounder*—this action implements an AM for northern windowpane flounder for fishing year 2015 due to an overage of the 2014 catch limit for this stock. This AM requires sector and common pool vessels to use selective trawl gear when fishing in certain areas on GB.

• *Daily catch reporting for commercial groundfish vessels*—this action implements a requirement that commercial groundfish vessels submit a daily catch report through the Vessel Monitoring System (VMS) when declared into the GOM broad stock area and any other broad stock area on the same trip. Groundfish vessels must currently submit trip-level reports. However, we have the authority to modify the frequency of reporting, if necessary.

• *Other regulatory corrections*—we are implementing several revisions to the regulations to correct references, remove unnecessary text, and make other minor edits. Each correction is described in the section ''11. Regulatory Corrections Under Regional Administrator Authority.''

## 2. Status Determination Criteria

The Northeast Fisheries Science Center (NEFSC) conducted stock assessments in 2014 for GOM cod, GOM haddock, GOM winter flounder, GB yellowtail flounder, GB winter flounder, and pollock. To incorporate the results of these assessments, this action changes the status determination for GB yellowtail flounder to unknown and updates the numerical estimates of the status determination criteria for the remaining stocks. Table 1 provides the updated numerical estimates of the status determination criteria, and Table 2 summarizes changes in stock status based on the new stock assessments conducted in 2014.

Although status determination relative to reference points is unknown for GB yellowtail flounder, the best scientific information available

indicates that stock status is poor. The changes to the status determination criteria implemented in this action do not affect the rebuilding plan for this stock, which has an end date of 2032. Although biomass estimates are not currently available, to ensure that rebuilding progress is made, catch limits will continue to be set at levels at which the Transboundary Resources Assessment Committee and the Council's Scientific and Statistical Committee (SSC) determine will prevent overfishing. Additionally, at whatever point the stock assessment for GB yellowtail flounder can provide numerical estimates of status determination criteria, those estimates will be used to evaluate progress towards the existing rebuilding targets.

TABLE 1—NUMERICAL ESTIMATES OF STATUS DETERMINATION CRITERIA

| Stock | Biomass target $SSB_{MSY}$ or proxy (mt) | Maximum fishing mortality threshold ($F_{MSY}$ or proxy) | MSY (mt) |
|---|---|---|---|
| GOM Cod: | | | |
| M=0.2 Model | 47,184 | 0.18 | 7,753 |
| $M_{ramp}$ Model | 69,621 | 0.18 | 11,388 |
| GOM Haddock | 4,108 | 0.46 | 955 |
| GOM Winter Flounder | n/a | 0.23 exploitation rate | n/a |
| GB Yellowtail Flounder | n/a | n/a | n/a |
| GB Winter Flounder | 8,100 | 0.44 | 3,200 |
| Pollock | 76,900 | 0.42 (equivalent to $F_{5-7}$ = 0.27) | 14,800 |

SSB = Spawning Stock Biomass; MSY = Maximum Sustainable Yield; F = Fishing Mortality; M = Natural Mortality
**Note.** An explanation of the two assessment models for GOM cod is provided in the section "4. Fishing Years 2015–2017 Catch Limits."

TABLE 2—SUMMARY OF CHANGES TO STOCK STATUS

| Stock | Previous assessment | | 2014 assessment | |
|---|---|---|---|---|
| | Overfishing? | Overfished? | Overfishing? | Overfished? |
| GOM Cod | Yes | Yes | Yes | Yes |
| GOM Haddock | Yes | No [1] | No | No |
| GOM Winter Flounder | No | Unknown | No | Unknown |
| GB Yellowtail Flounder | Yes | Yes | Unknown | Unknown |
| GB Winter Flounder | No | No | No | No |
| Pollock | No | No | No | No |

[1] Stock was approaching an overfished condition

### 3. Fishing Year 2015 U.S./Canada Quotas

As described in the proposed rule, eastern GB cod, eastern GB haddock, and GB yellowtail flounder are jointly managed with Canada under the U.S./Canada Resource Sharing Understanding. This action adopts shared U.S./Canada quotas for these stocks for fishing year 2015 based on 2014 assessments and the recommendations of the Transboundary Management Guidance Committee (TMGC) (Table 3). For a more detailed discussion of the TMGC's 2015 catch advice, see the TMGC's guidance document at: *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies/index.html*.

TABLE 3—FISHING YEAR 2015 U.S./CANADA QUOTAS (mt, LIVE WEIGHT) AND PERCENT OF QUOTA ALLOCATED TO EACH COUNTRY

| Quota | Eastern GB Cod | Eastern GB Haddock | GB Yellowtail Flounder |
|---|---|---|---|
| Total Shared Quota | 650 | 37,000 | 354 |
| U.S. Quota | 124 (19%) | 17,760 (48%) | 248 (70%) |
| Canada Quota | 526 (81%) | 19,240 (52%) | 106 (30%) |

The regulations implementing the U.S./Canada Resource Sharing Understanding require that any overages of the U.S. quota for eastern GB cod, eastern GB haddock, or GB yellowtail flounder be deducted from the U.S. quota in the following fishing year. If fishing year 2014 catch information indicates that the U.S. fishery exceeded its quota for any of the shared stocks, we must reduce the respective U.S. quota for fishing year 2015 in a future management action, as close to May 1, 2015, as possible. If any fishery that is allocated a portion of the U.S. quota exceeds its allocation, and causes an overage of the overall U.S. quota, the overage reduction would only be applied to that fishery's allocation in the following fishing year. This ensures that catch by one component of the fishery does not negatively affect another component of the fishery.

### 4. Fishing Years 2015–2017 Catch Limits

This action adopts fishing years 2015–2017 catch limits for GOM cod, GOM haddock, GOM winter flounder, GB winter flounder, GB yellowtail flounder (2015–2016 only), and pollock based on the 2014 assessments for these stocks. In addition, this action updates the 2015 catch limits for GB cod and GB haddock based on the U.S./Canada quotas for the

portions of these stocks jointly managed with Canada. For all other stocks, the overall catch limits included in this rule are the same as those previously adopted in the final rules implementing Framework 50 and Framework 51 to the FMP, although small changes have been made to the distribution of these catch limits to the various components of the fishery. The catch limits implemented in this action, including overfishing limits (OFLs), acceptable biological catches (ABCs), and annual catch limits (ACLs), can be found in Tables 4 through 12. A summary of how these catch limits were developed, including the distribution to the various fishery components, was provided in the proposed rule. Additional information on the development of these catch limits is also provided in the Framework 53 Environmental Assessment and its supporting appendices.

The sector and common pool catch limits implemented in this action are based on potential sector contributions (PSCs) for fishing year 2015 and fishing year 2014 sector rosters. 2015 sector rosters will not be finalized until May 1, 2015, because individual permit holders have until the end of the 2014 fishing year (April 30, 2015) to drop out of a sector and fish in the common pool fishery for 2015. Therefore, it is possible that the sector and common pool catch limits in this action may change due to changes in the sector rosters. If changes to the sector rosters occur, updated catch limits will be announced as soon as possible in the 2015 fishing year to reflect the final sector rosters as of May 1, 2015. Sector specific allocations for each stock can be found in the final rule for 2015–2016 Sector Operations Plans and Contracts.

There are no catch limits adopted for fishing years 2016 or 2017 for most groundfish stocks. Stock assessment updates for all groundfish stocks are scheduled for September 2015, and, based on these assessment updates, catch limits will be set in a future action for fishing years 2016–2018. Given the timing of the stock assessments, the management action for the 2016 fishing year is not expected to be completed by the start of the fishing year. As a result, this action adopts default catch limits that would be implemented on May 1, 2016, to prevent disruption to the fishery (see the section ''6. Default Catch Limits'').

TABLE 4—FISHING YEARS 2015–2017 OVERFISHING LIMITS AND ACCEPTABLE BIOLOGICAL CATCHES

[mt, live weight]

| Stock | 2015 | | 2016 | | 2017 | |
|---|---|---|---|---|---|---|
| | OFL | U.S. ABC | OFL | U.S. ABC | OFL | U.S. ABC |
| GB Cod | 4,191 | 1,980 | | | | |
| GOM Cod | 514 | 386 | 514 | 386 | 514 | 386 |
| GB Haddock | 56,293 | 24,366 | | | | |
| GOM Haddock | 1,871 | 1,454 | 2,270 | 1,772 | 2,707 | 2,125 |
| GB Yellowtail Flounder | | 248 | | 354 | | |
| SNE/MA Yellowtail Flounder | 1,056 | 700 | | | | |
| CC/GOM Yellowtail Flounder | 1,194 | 548 | | | | |
| American Plaice | 2,021 | 1,544 | | | | |
| Witch Flounder | 1,846 | 783 | | | | |
| GB Winter Flounder | 3,242 | 2,010 | 3,383 | 2,107 | 3,511 | 2,180 |
| GOM Winter Flounder | 688 | 510 | 688 | 510 | 688 | 510 |
| SNE/MA Winter Flounder | 4,439 | 1,676 | | | | |
| Redfish | 16,845 | 11,974 | | | | |
| White Hake | 6,237 | 4,713 | 6,314 | 4,645 | | |
| Pollock | 21,538 | 16,600 | 21,864 | 16,600 | 24,598 | 16,600 |
| N. Windowpane Flounder | 202 | 151 | | | | |
| S. Windowpane Flounder | 730 | 548 | | | | |
| Ocean Pout | 313 | 235 | | | | |
| Atlantic Halibut | 198 | 100 | | | | |
| Atlantic Wolffish | 94 | 70 | | | | |

SNE/MA = Southern New England/Mid-Atlantic; CC = Cape Cod; N = Northern; S = Southern.
**Note:** An empty cell indicates no OFL/ABC is adopted for that year. These catch limits will be set in a future action.

*Gulf of Maine Cod*

A detailed summary of the GOM cod stock assessment, and the development of catch limits for the 2015–2017 fishing years, was provided in the proposed rule to this action, and is not repeated here. In the proposed rule, we made a preliminary determination that an ABC of 386 mt would meet necessary conservation objectives, but requested additional comment on some aspects of this ABC. We received a number of comments in response to this request, including additional catch projections to better illustrate the potential biological impacts of various catch scenarios. After considering public comment, supporting analysis, and the best scientific information available, we have determined that an ABC of 386 mt is appropriate and consistent with the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the National Standards. As described below, this ABC balances other Magnuson-Stevens Act objectives, including achieving optimum yield and taking into account the needs of fishing communities, without compromising conservation objectives to prevent overfishing and rebuild the stock. In light of current stock conditions, this ABC is a 75-percent reduction compared to 2014, which is in addition to the 80-percent reduction implemented for fishing years 2013–2014. In total, the GOM cod catch limit has been reduced by 95 percent over the last 5 years.

We are approving an ABC of 386 mt with the expectation that the catch limits implemented in this final rule will be reviewed following the September 2015 assessment for GOM cod. This assessment is intended to be incorporated for fishing year 2016. Fishing years 2016–2018 catch limits for GOM cod would be set based on the September 2015 assessment, and would replace the 2016–2017 catch limits adopted in this final rule. Uncertainties in catch projections can be exacerbated if 3-year specifications are set and

remain unchecked without additional stock assessment information. However, in this case, we determined that concerns for past performance, and the risk of erring in setting the ABC, are largely mitigated given the pending 2015 assessment. Therefore, our approval of the GOM cod ABC is, effectively, only approval for the first year of the remaining rebuilding time period.

As described more fully in the proposed rule, the SSC initially recommended an OFL of 514 mt and a provisional ABC of 200 mt for fishing years 2015–2017 based on catch scenarios that the Council's Groundfish Plan Development Team (PDT) presented. One provision of the ABC control rule in the FMP specifies that catch limits be based on 75 percent of $F_{MSY}$ or $F_{rebuild}$, whichever is lower. As part of the 2014 assessment, catch projections were updated, and $F_{rebuild}$ was calculated as the constant F required to rebuild the stock by 2024. The SSC's provisional ABC recommendation of 200 mt was the midpoint between the $F_{rebuild}$ catch for the scenario in which natural mortality is 0.2 and the scenario in which natural mortality increases, but returns to 0.2. This provisional ABC did not incorporate the projection that assumes natural mortality remains at 0.4, and that suggests rebuilding is not possible. As a result, the SSC determined that this provisional ABC was not consistent with its OFL recommendation, which was developed by averaging the 2015 $F_{MSY}$ catches from all three catch projections.

Following discussion about the rebuilding potential of GOM cod, and the catch projection that indicates rebuilding is not possible, the SSC requested that the PDT provide analysis of the incidental catch of GOM cod. This request was in recognition of the ABC control rule that specifies that, if a stock cannot rebuild in the specified rebuilding period, even with no fishing, the ABC should be based on incidental bycatch, including a reduction in the bycatch rate. Based on analysis presented by the PDT, the SSC determined that the overall incidental catch of GOM cod was approximately 500–600 mt for the 2013 fishing year under the current operating conditions of the fishery. After consideration of this information, and examination of the available assessment information, the SSC recommended an ABC of 386 mt, which was calculated by taking 75 percent of the OFL. This recommendation was an attempt to balance the various natural mortality scenarios and catch projections from the two assessment models with the various provisions of the ABC control rule. Similar to our conditional approval of the ABC, the SSC noted that it expected to revisit its catch advice for fishing years 2016–2017 following the 2015 assessment update.

The PDT updated the catch projections following the SSC's final ABC recommendation. These projections, along with the biological impacts analysis, indicate that an ABC of 386 mt has a 6- to 33-percent probability of overfishing in fishing year 2015. Although recognizing that catch projections can be optimistic, these probabilities are well below the median, and indicate that the ABC is sufficiently below the OFL to prevent overfishing. Further, for the two projection scenarios that indicate that rebuilding can occur, an ABC of 386 mt for fishing years 2015–2017 would still rebuild the stock by 2024. All of the available catch projections indicate that an ABC of 386 mt would result in a fishing mortality rate of 0.13–0.11, which would be the lowest fishing mortality rate in the assessment time series. This estimated fishing mortality rate would be an 80-percent reduction from the estimated 2014 fishing mortality rate, and a 90-percent reduction from the fishing mortality rate estimated for 2013.

The catch projections that the PDT completed for the biological impacts analysis indicate that rebuilding could still occur under a 386-mt ABC for the 2015–2017 fishing years. However, since we published the proposed rule, we further examined various catch projection scenarios to better understand the trade-offs associated with an ABC of 386 mt. Based on this evaluation, a catch of 386 mt in fishing year 2015 is expected to have little functional difference in future catches and biomass compared to the 200-mt option that the SSC initially considered, but did not recommend. This is, in part, because catches would be lower under the 386-mt scenario in the out years of the rebuilding period compared to those needed under a catch of 200 mt. Considering this, we determined that an ABC of 386 mt would meet conservation objectives, and allow rebuilding to occur by 2024, while still trying to balance the need to achieve optimum yield for the groundfish fishery, as well as mitigate the economic impacts of the GOM cod catch limit, to the extent practicable.

An ABC of 386 mt is expected to have substantial economic impacts on groundfish vessels, which are summarized later in this preamble. These impacts are expected to be disproportionately distributed among the groundfish fleet. The largest revenue reductions are expected for small vessels less than 50 ft (15 m), and those fishing from Gloucester, MA, and New Hampshire ports. The economic impacts of the GOM cod ABC implemented in this final rule are expected to be substantially greater than previous catch limit reductions for GOM cod and other groundfish stocks.

Based on incidental catch information compiled by the PDT, an ABC of 386 mt is below the estimate of incidental catch of GOM cod that occurred in fishing year 2013. Incidental catch is largely a function of the overall ACL given the AMs in place for groundfish vessels. However, this information is illustrative of potential fishery operations under an ABC of 386 mt, which are expected to be greatly restricted, and in some cases eliminated.

In fishing year 2013, when the ACL was reduced by 80 percent, incidental catch was estimated to be approximately 500–600 mt. Beginning in fishing year 2013, sectors primarily used their GOM cod allocation to access other groundfish stocks. Multiple sources of information indicate a marked decline in directed fishing for GOM cod. With an additional 75-percent reduction beginning in fishing year 2015, the incentive to target GOM cod is virtually eliminated, and the fishery will be, in effect, a ''bycatch-only'' fishery. The average GOM cod allocation for a sector will be 23,000 lb (10,433 kg), and many sectors will receive allocations less than 10,000 lb (4,536 kg). In addition, the recreational fishery will be prohibited from possessing GOM cod. Even under this incidental catch scenario, the GOM cod ABC is expected to severely restrict catch of other groundfish stocks, particularly GOM haddock, pollock, redfish, and some flatfish.

We remain concerned about GOM cod stock status, and will continue to carefully consider management measures for this stock. The ABC we are implementing in this action is a complex balance between conservation objectives and other Magnuson-Stevens Act requirements. In an effort to closely monitor stock indicators, we reviewed the recent fall 2014 NEFSC bottom trawl survey indices. The fall survey indicated a small increase compared to 2012 and 2013; however, the general trend of survey indices, as well as recruitment, remains very low. While the updated survey information may provide an initial, and potentially positive, indication of improvement, it is difficult to anticipate the results of the full 2015 assessment. We will continue to carefully monitor stock indicators leading into the 2015

assessment to fully inform our re-evaluation of the GOM cod catch limit, and the balancing of conservation and management objectives.

Further, one concern we raised during the development of Framework 53, and in the proposed rule, is the importance of controlling fishing mortality to help ensure that conservation objectives are met. Available analyses suggest that an extremely low catch limit for GOM cod may create an economic incentive to misreport catch, and, if this occurs, could reduce the accuracy of catch apportionment. Information indicates that this incentive increases as the GOM cod catch limit is further reduced. To help ensure correct catch apportionment and compliance with the GOM cod ACL adopted in this action, we are also implementing an additional reporting requirement for common pool and sector vessels fishing in multiple broad stock areas on the same trip. This additional reporting requirement is described in the section ''10. Daily Catch Reporting for Commercial Groundfish Vessels.''

TABLE 5—FISHING YEAR 2015 CATCH LIMITS

[mt, live weight]

| Stock | Total ACL | Total groundfish fishery | Preliminary sector | Preliminary common pool | Recreational fishery | Midwater trawl fishery | Scallop fishery | Small-mesh fisheries | State waters sub-component | Other sub-component |
|---|---|---|---|---|---|---|---|---|---|---|
| GB Cod | 1,886 | 1,787 | 1,753 | 34 | | | | | 20 | 79 |
| GOM Cod | 366 | 328 | 202 | 5 | 121 | | | | 26 | 13 |
| GB Haddock | 23,204 | 21,759 | 21,603 | 156 | | 227 | | | 244 | 975 |
| GOM Haddock | 1,375 | 1,329 | 949 | 9 | 372 | 14 | | | 11 | 21 |
| GB Yellowtail Flounder | 240 | 195 | 192 | 3 | | | 38 | 5 | na | 2 |
| SNE/MA Yellowtail Flounder | 666 | 557 | 457 | 102 | | | 66 | | 14 | 28 |
| CC/GOM Yellowtail Flounder | 524 | 458 | 442 | 16 | | | | | 38 | 27 |
| American Plaice | 1,470 | 1,408 | 1,381 | 27 | | | | | 31 | 31 |
| Witch Flounder | 751 | 610 | 598 | 12 | | | | | 23 | 117 |
| GB Winter Flounder | 1,952 | 1,891 | 1,876 | 15 | | | | | na | 60 |
| GOM Winter Flounder | 489 | 392 | 375 | 18 | | | | | 87 | 10 |
| SNE/MA Winter Flounder | 1,607 | 1,306 | 1,149 | 157 | | | | | 117 | 184 |
| Redfish | 11,393 | 11,034 | 10,974 | 60 | | | | | 120 | 239 |
| White Hake | 4,484 | 4,343 | 4,311 | 32 | | | | | 47 | 94 |
| Pollock | 15,878 | 13,720 | 13,628 | 92 | | | | | 996 | 1,162 |
| N. Windowpane Flounder | 144 | 98 | na | 98 | | | | | 2 | 44 |
| S. Windowpane Flounder | 527 | 102 | na | 102 | | | 183 | | 55 | 186 |
| Ocean Pout | 220 | 195 | na | 195 | | | | | 2 | 24 |
| Atlantic Halibut | 97 | 64 | na | 64 | | | | | 30 | 3 |
| Atlantic Wolffish | 65 | 62 | na | 62 | | | | | 1 | 3 |

TABLE 6—FISHING YEAR 2016 CATCH LIMITS

[mt, live weight]

| Stock | Total ACL | Total groundfish fishery | Preliminary sector | Preliminary common pool | Recreational fishery | Midwater trawl fishery | Scallop fishery | Small-mesh fisheries | State waters sub-component | Other sub-component |
|---|---|---|---|---|---|---|---|---|---|---|
| GOM Cod | 366 | 328 | 202 | 5 | 121 | | | | 26 | 13 |
| GOM Haddock | 1,675 | 1,620 | 1,155 | 12 | 453 | 16 | | | 13 | 26 |
| GB Yellowtail Flounder | 343 | 278 | 274 | 4 | | | 55 | 7 | na | 4 |
| GB Winter Flounder | 2,046 | 1,982 | 1,967 | 15 | | | | | na | 63 |
| GOM Winter Flounder | 489 | 392 | 375 | 18 | | | | | 87 | 10 |
| White Hake | 4,420 | 4,280 | 4,249 | 31 | | | | | 46 | 93 |
| Pollock | 15,878 | 13,720 | 13,628 | 92 | | | | | 996 | 1,162 |

TABLE 7—FISHING YEAR 2017 CATCH LIMITS

[mt, live weight]

| Stock | Total ACL | Total groundfish fishery | Preliminary sector | Preliminary common pool | Recreational fishery | Midwater trawl fishery | State waters sub-component | Other sub-component |
|---|---|---|---|---|---|---|---|---|
| GOM Cod | 366 | 328 | 202 | 5 | 121 | | 26 | 13 |
| GOM Haddock | 2,009 | 1,943 | 1,386 | 14 | 543 | 20 | 15 | 31 |
| GB Winter Flounder | 2,117 | 2,051 | 2,035 | 16 | | | na | 65 |
| GOM Winter Flounder | 489 | 392 | 375 | 18 | | | 87 | 10 |

TABLE 7—FISHING YEAR 2017 CATCH LIMITS—Continued

[mt, live weight]

| Stock | Total ACL | Total groundfish fishery | Preliminary sector | Preliminary common pool | Recreational fishery | Midwater trawl fishery | State waters sub-component | Other sub-component |
|---|---|---|---|---|---|---|---|---|
| Pollock | 15,878 | 13,720 | 13,628 | 92 | ..... | ..... | 996 | 1,162 |

TABLE 8—FISHING YEARS 2015–2017 COMMON POOL TRIMESTER TOTAL ALLOWABLE CATCHES

[mt, live weight]

| Stock | 2015 | | | 2016 | | | 2017 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Trimester 1 | Trimester 2 | Trimester 3 | Trimester 1 | Trimester 2 | Trimester 3 | Trimester 1 | Trimester 2 | Trimester 3 |
| GB Cod | 8.6 | 12.7 | 13.1 | ..... | ..... | ..... | ..... | ..... | ..... |
| GOM Cod | 1.3 | 1.7 | 1.8 | 1.3 | 1.7 | 1.8 | 1.3 | 1.7 | 1.8 |
| GB Haddock | 42.0 | 51.3 | 62.2 | ..... | ..... | ..... | ..... | ..... | ..... |
| GOM Haddock | 2.56 | 2.47 | 4.46 | 3.1 | 3.0 | 5.4 | 3.7 | 3.6 | 6.5 |
| GB Yellowtail Flounder | 0.6 | 0.9 | 1.6 | 0.9 | 1.4 | 2.3 | ..... | ..... | ..... |
| SNE/MA Yellowtail Flounder | 21.4 | 37.7 | 42.8 | ..... | ..... | ..... | ..... | ..... | ..... |
| CC/GOM Yellowtail Flounder | 5.5 | 5.5 | 4.7 | ..... | ..... | ..... | ..... | ..... | ..... |
| American Plaice | 6.6 | 9.9 | 11.0 | ..... | ..... | ..... | ..... | ..... | ..... |
| Witch Flounder | 3.4 | 3.8 | 5.2 | ..... | ..... | ..... | ..... | ..... | ..... |
| GB Winter Flounder | 1.2 | 3.5 | 10.1 | 1.2 | 3.7 | 10.5 | 1.3 | 3.8 | 10.9 |
| GOM Winter Flounder | 6.5 | 6.6 | 4.4 | 6.5 | 6.6 | 4.4 | 6.5 | 6.6 | 4.4 |
| Redfish | 14.9 | 18.5 | 26.2 | ..... | ..... | ..... | ..... | ..... | ..... |
| White Hake | 12.0 | 9.8 | 9.8 | 11.9 | 9.7 | 9.7 | ..... | ..... | ..... |
| Pollock | 25.7 | 32.1 | 33.9 | 25.7 | 32.1 | 33.9 | 25.7 | 32.1 | 33.9 |

**Note.** An empty cell indicates that no catch limit has been set yet for the stock. These catch limits will be set in a future management action.

TABLE 9—FISHING YEARS 2015–2016 COMMON POOL INCIDENTAL TOTAL ALLOWABLE CATCHES

[mt, live weight]

| Stock | Percent of common pool sub-ACL | 2015 | 2016 |
|---|---|---|---|
| GB Cod | 2 | 0.69 | na |
| GOM Cod | 1 | 0.05 | 0.05 |
| GB Yellowtail Flounder | 2 | 0.06 | 0.09 |
| CC/GOM Yellowtail Flounder | 1 | 0.16 | na |
| American Plaice | 5 | 1.37 | na |
| Witch Flounder | 5 | 0.62 | na |
| SNE/MA Winter Flounder | 1 | 1.57 | na |

TABLE 10—PERCENT OF INCIDENTAL TOTAL ALLOWABLE CATCH ALLOCATED TO EACH SPECIAL MANAGEMENT PROGRAM

| Stock | Regular B Days-at-Sea program | Closed Area I hook gear Haddock SAP | Eastern U.S./Canada Haddock SAP |
|---|---|---|---|
| GB Cod | 50 | 16 | 34 |
| GOM Cod | 100 | ..... | ..... |
| GB Yellowtail Flounder | 50 | ..... | 50 |
| CC/GOM Yellowtail Flounder | 100 | ..... | ..... |
| American Plaice | 100 | ..... | ..... |
| Witch Flounder | 100 | ..... | ..... |
| SNE/MA Winter Flounder | 100 | ..... | ..... |
| White Hake | 100 | ..... | ..... |

SAP = Special Access Program.

TABLE 11—FISHING YEARS 2015–2016 COMMON POOL INCIDENTAL TOTAL ALLOWABLE CATCHES FOR EACH SPECIAL MANAGEMENT PROGRAM

[mt, live weight]

| Stock | Regular B Days-at-Sea program | | Closed Area I hook gear Haddock SAP | | Eastern U.S./Canada Haddock SAP | |
|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2015 | 2016 | 2015 | 2016 |
| GB Cod | 0.34 | na | 0.11 | na | 0.23 | na |
| GOM Cod | 0.05 | 0.05 | ..... | ..... | ..... | ..... |

TABLE 11—FISHING YEARS 2015–2016 COMMON POOL INCIDENTAL TOTAL ALLOWABLE CATCHES FOR EACH SPECIAL MANAGEMENT PROGRAM—Continued

[mt, live weight]

| Stock | Regular B Days-at-Sea program | | Closed Area I hook gear Haddock SAP | | Eastern U.S./Canada Haddock SAP | |
|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2015 | 2016 | 2015 | 2016 |
| GB Yellowtail Flounder | 0.03 | 0.05 | ..... | ..... | 0.03 | 0.05 |
| CC/GOM Yellowtail Flounder | 0.16 | na | ..... | ..... | ..... | ..... |
| American Plaice | 1.37 | na | ..... | ..... | ..... | ..... |
| Witch Flounder | 0.62 | na | ..... | ..... | ..... | ..... |
| SNE/MA Winter Flounder | 1.57 | na | ..... | ..... | ..... | ..... |

TABLE 12—FISHING YEAR 2015 CLOSED AREA I HOOK GEAR HADDOCK SPECIAL ACCESS PROGRAM TOTAL ALLOWABLE CATCH

[mt, live weight]

| Exploitable biomass | Western GB $B_{2015}$[1] | Western GB $B_{Year}/B_{2004}$ | Total allowable catch |
|---|---|---|---|
| 169,027 | 59,159 | 2.166 | 2,448 |

[1] The western GB exploitable biomass is assumed to be 35 percent of the total exploitable biomass.

**5. Gulf of Maine Cod Protection Measures**

This action re-configures the GOM rolling closures and prohibits possession of GOM cod for the recreational fishery. The GOM cod protection closures implemented in this final rule are summarized in Table 13 and Figure 1. These closures apply to all federally permitted commercial vessels, except for commercial vessels that are fishing with exempted gear or in an exempted fishery. Additionally, these closures do not apply to commercial vessels that are fishing exclusively in state waters provided the vessel does not have a Federal multispecies permit. As adopted in Amendment 16 to the FMP, sector vessels are exempt from the closures in March and October. The March and October closures also do not apply to Handgear A vessels, regardless of whether the vessel was fishing in the common pool or in a sector.

Exempted gear, as defined in § 648.2, is deemed to be not capable of catching groundfish and currently includes: Pelagic hook and line; pelagic longline; spears; rakes; diving gear; cast nets; tongs; harpoons; weirs; dipnets; stop nets; pound nets; pelagic gillnets; pots and traps; shrimp trawls (with a properly configured grate); and surfclam and ocean quahog dredges. Based on the current list of approved exempted fisheries defined in § 648.80, the GOM cod protection closures do not apply to vessels fishing in the Midwater Trawl Gear Exempted Fishery, the Purse Seine Gear Exempted Fishery, the Raised Footrope Trawl Exempted Whiting Fishery, the Small Mesh Area 2 Exemption Area, or the Scallop Dredge Exemption Area. Only the exempted fisheries that overlap in time and area with the cod protection closures are listed here. This list may change if any changes are made to exempted fisheries, or the protection closures, in a future action.

TABLE 13—GULF OF MAINE COD PROTECTION CLOSURES

| Month | Area Closures (30 minute square) |
|---|---|
| May | *All Vessels:* 125 north of 42°20′ N. lat., 132, 133, 138, 139, 140. |
| June | *All Vessels:* 125 north of 42°20′ N. lat., 132, 139, 140, 146, 147. |
| July | None. |
| August | None. |
| September | None. |
| October | *Non-Sector Vessels:* 124, 125. |
| November | *All Vessels:* Portion of 124, 125. |
| December | *All Vessels:* Portion of 124, 125. |
| January | *All Vessels:* Portion of 124, 125. |
| February | None. |
| March | *Non-Sector Vessels:* 121, 122, 123. |
| April | None. |

**Note:** Handgear A vessels are exempt from the same closures as sector vessels.

The GOM cod closures are intended to protect spawning GOM cod, reduce fishing mortality on GOM cod, and provide additional fishing opportunities for groundfish vessels to target healthy groundfish stocks in areas that were previously closed. These closures are subject to review when the GOM cod spawning stock biomass reaches the minimum biomass threshold (50 percent of $SSB_{MSY}$). However, as we noted in the proposed rule, the Council could review and modify these closures at any time. Given the pending 2015 assessment, and additional spawning research, reviewing these protection closures as new information becomes available is likely more important than waiting for the minimum biomass threshold to be met. We also highlight a number of concerns below for April, and the Council could consider changes to GOM area closures in light of these concerns. Additionally, as we described in the proposed rule, given the extremely low GOM cod allocation, it is difficult to predict how groundfish vessels will operate in 2015, and we expect the number of active groundfish vessels could markedly decline. We intend to monitor fishing effort following the implementation of management measures for the 2015 fishing year to ensure that any effort changes do not undermine the effectiveness of the protection closures.

The protection closures are an additional tool the Council is using to protect GOM cod, and are complementary to its requirement for setting catch limits that will prevent overfishing and help rebuild the stock. Based on the available information, protecting spawning GOM cod could help improve the chances of successful spawning events, and, as a result, help prevent failures of future year classes. Thus, the biological objective of these closures is to help prevent further biomass declines and improve the

likelihood of rebuilding GOM cod. In light of the low GOM cod catch limit, the protection closures were also designed to balance these biological objectives with access to healthy groundfish stocks.

We highlighted some concerns in the proposed rule for the re-configuration of the GOM area closures. There are biological and economic trade-offs associated with the new closures, and we considered these trade-offs carefully. Available information suggests that once a specific spawning aggregation is lost, there is little indication that the aggregation could recover. As a result, we determined that the addition of winter closures is important because there are currently no protections for the winter spawning component. If the removal of April closures was recommended in isolation, with no additional spring or winter closures, we likely would have disapproved this measure. We determined, however, that the closed area recommendations for the winter and April time periods were presented as a package reflecting the Council's balancing of conservation benefits and impacts on the fishing industry, and, as such, could not be approved or disapproved independent of each other without undermining the Council's intent.

With the approval of the new area closures for GOM cod, we reiterate our concerns for the potential of the April opening to have negative impacts on other groundfish stocks that spawn in the spring. A number of these stocks are in poor condition (*e.g.,* GOM winter flounder, CC/GOM yellowtail flounder), and, for plaice, the second 10-year rebuilding program was implemented in 2014 due to inadequate rebuilding progress. As we noted previously in this rule, we also remain concerned about GOM cod given its poor condition. The protection closures implemented in this final rule are closely related to measures under consideration in the Council's Habitat Omnibus Amendment 2. We will continue to work with the Council to help ensure the goals and objectives of that Amendment are met.

Recreational vessels are not subject to the GOM cod protection closures and could continue to fish in these areas. Federally permitted party and charter vessels are still required to obtain a letter of authorization to fish in the GOM closed areas. In lieu of the protection closures, this action adopts a prohibition on possession of GOM cod for all private recreational vessels fishing in Federal waters, and all federally permitted party and charter vessels. This is intended to reduce recreational fishing mortality on GOM cod, by reducing the incentive to target the stock, while still providing recreational vessels the opportunity to target other healthy groundfish stocks. Recent catch projections indicated that the recreational fishery would still exceed its allocation for GOM cod in the 2015 fishing year, due to bycatch, even with the prohibition on possession that is implemented in this action. Therefore, in a separate rulemaking, we are adopting additional recreational measures under our discretionary authority to help ensure the recreational fishery does not exceed its allocation for the 2015 fishing year.

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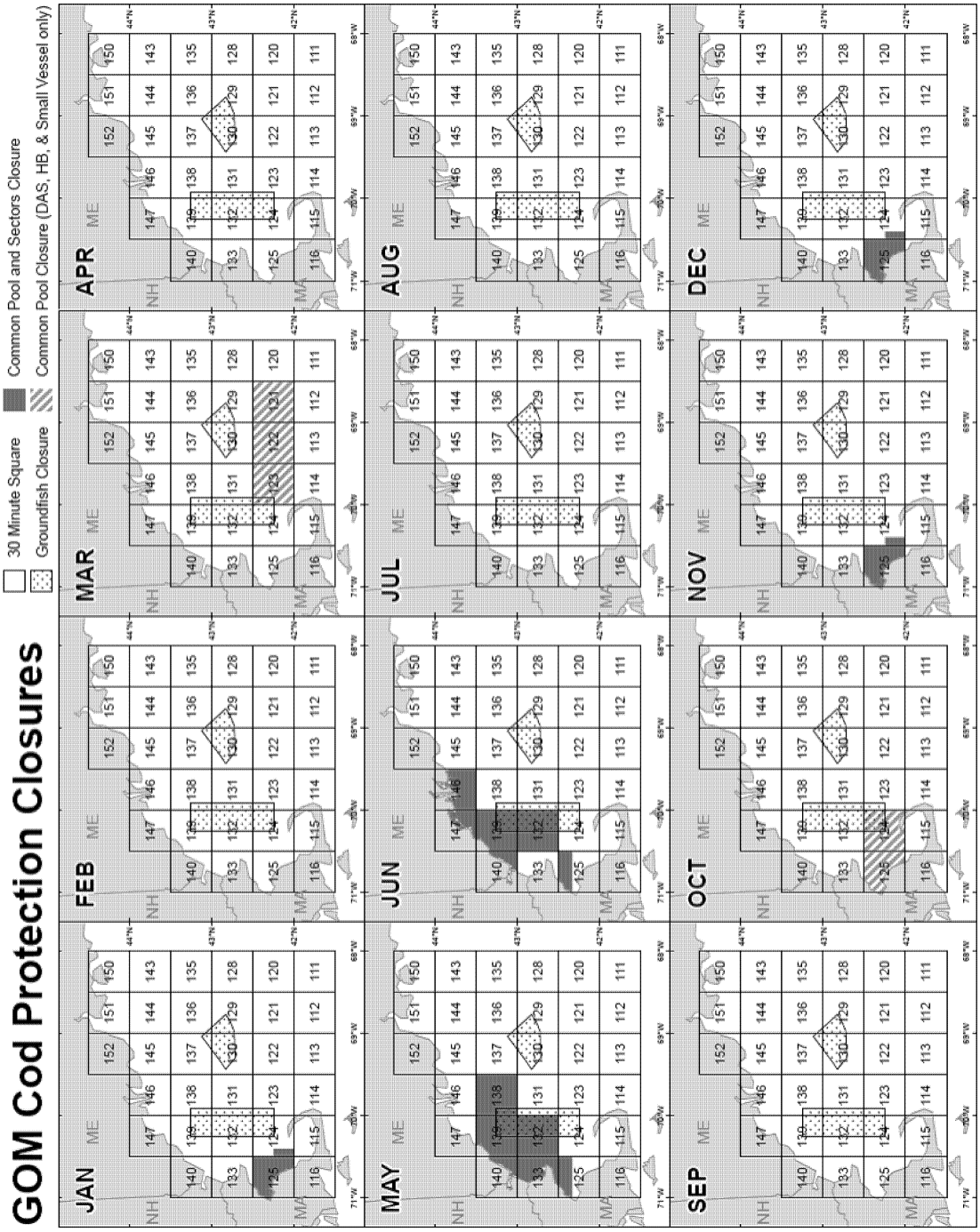
**Figure 1. Gulf of Maine Cod Protection Closures**

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### 6. Default Catch Limits

*Mechanism for Setting Default Catch Limits*

This action establishes a mechanism for setting default catch limits in the event a future management action is delayed. If final catch limits have not been implemented by the start of a fishing year on May 1, then default catch limits will be set at 35 percent of the previous year's catch limit. If this value exceeds the Council's recommendation for the upcoming fishing year, the default catch limits will be reduced to an amount equal to the Council's recommendation for the upcoming fishing year. Because groundfish vessels are not able to fish if final catch limits have not been implemented, this measure is intended to prevent disruption to the groundfish fishery if final catch limits are not in place by May 1.

Each time a specifications action is implemented, we intend to also announce the default catch limits that would go into place for the out year in the event a future management action is delayed. Once the Council's recommendation is known for that year, we will determine if any of the default catch limits previously set would exceed the Council's recommendation. If so, we will reduce the default catch limits consistent with the Council's recommendation, and will announce this adjustment prior to the start of the fishing year on May 1. For example, if a framework action sets catch limits for the 2016–2018 fishing year, we would

announce the default catch limits for fishing year 2019 in the same final rule implementing the final 2016–2018 catch limits. If necessary, prior to the start of the 2019 fishing year, we will evaluate whether any of the default catch limits previously announced exceed the Council's recommendation for 2019. If so, we would announce adjustments to the 2019 default catch limits prior to May 1, 2019.

The default catch limits would be in place from May 1 through July 31, unless a final rule including finalized catch limits is implemented prior to July 31 that replaces the default catch limits. If final catch limits are not implemented by the end of the default specifications period, then no catch limits would be in place beginning on August 1. Under this scenario, commercial groundfish vessels would be unable to fish until final catch limits and allocations were implemented for the fishing year. All catch occurring while default catch limits are in place will be attributed to the appropriate fishery allocation and the final catch limits for the fishing year.

The default catch limits will be distributed to the various components of the fishery based on the distribution adopted by the Council for the previous fishing year. Additionally, this measure does not change any of the existing AMs for any fishery. For example, if a sector catches its entire allocation of redfish specified for the default specifications time period, it will be prohibited from fishing in the redfish stock area until final specifications were set, or it leased additional allocation for this stock. The midwater trawl fishery is the only non-groundfish fishery with an inseason AM for its allocation of GOM and GB haddock. When the GOM or GB haddock catch cap specified for the default specifications period is caught, the directed herring fishery will be closed for all herring vessels fishing with midwater trawl gear for the remainder of the default specifications time period, unless final specifications were set prior to July 31. For other non-groundfish fisheries that receive an allocation (*e.g.,* scallop, small-mesh), this measure will not affect current operations because these fisheries do not currently have inseason AMs.

If default catch limits are implemented for any fishing year, groundfish sectors will not be subject to the 20-percent holdback of the prior year's allocation. This holdback provision was implemented in Amendment 16 to the FMP to allow time for processing end-of-year transfers and determine whether any overage reductions are necessary. However, the holdback provision will not be necessary under default catch limits because additional precaution has already been built in with the 65-percent reduction from the previous year's catch limits.

Although most FMPs implement default catch limits that are equal to the previous year's catch limits, a more precautionary approach was necessary for groundfish catch limits. In recent years, there have been a number of substantial reductions in groundfish catch limits, up to 80 percent. Given the frequency of large reductions, default catch limits equal to the previous year's catch limits could increase the risk of overfishing during the time period which default catch limits are implemented. As a result, reducing the default catch limits from the previous year's catch limits is intended to help ensure that overfishing does not occur during the default time period.

*Default Catch Limits for Fishing Year 2016*

Groundfish assessment updates are anticipated in September 2015, and these assessments are expected to be used to set catch limits for the 2016 fishing year beginning on May 1, 2016. However, due to the timing of these assessments, the Council's management action that will adopt the catch limits for the 2016 fishing year is not expected to be completed in time to be implemented by May 1, 2016. As a result, this action sets default limits for the 2016 fishing year that will become effective May 1, 2016, unless otherwise replaced by final specifications (Tables 14 and 15). This action only sets default catch limits for those groundfish stocks that would not have final specifications in place for 2016, absent another management action. If the default catch limits exceed the Council's recommendation for fishing year 2016, then they will be adjusted, as necessary, prior to May 1, 2016.

TABLE 14—FISHING YEAR 2016 DEFAULT SPECIFICATIONS

[mt, live weight]

| Stock | U.S. ABC | Total ACL | Groundfish sub-ACL | Preliminary sector sub-ACL | Preliminary common pool sub-ACL | Midwater trawl fishery |
|---|---|---|---|---|---|---|
| GB Cod | 693 | 660 | 625 | 614 | 12 | |
| GB Haddock | 8,528 | 8,121 | 7,616 | 7,563 | 53 | 79 |
| SNE/MA Yellowtail Flounder | 245 | 232 | 151 | 124 | 27 | |
| CC/GOM Yellowtail Flounder | 192 | 184 | 161 | 155 | 5 | |
| American Plaice | 540 | 514 | 492 | 483 | 9 | |
| Witch Flounder | 274 | 263 | 213 | 209 | 4 | |
| SNE/MA Winter Flounder | 587 | 563 | 457 | 402 | 56 | |
| Redfish | 4,191 | 3,988 | 3,862 | 3,846 | 16 | |
| N. Windowpane Flounder | 53 | 50 | 35 | na | 35 | |
| S. Windowpane Flounder | 192 | 184 | 36 | na | 36 | |
| Ocean Pout | 82 | 77 | 68 | na | 68 | |
| Atlantic Halibut | 35 | 34 | 22 | na | 22 | |
| Atlantic Wolffish | 25 | 23 | 22 | na | 22 | |

TABLE 15—FISHING YEAR 2016 DEFAULT COMMON POOL TRIMESTER TOTAL ALLOWABLE CATCHES

[mt, live weight]

| Stock | Trimester 1 | Trimester 2 | Trimester 3 |
|---|---|---|---|
| GB Cod | 3.0 | 4.4 | 4.5 |
| GB Haddock | 14.2 | 17.4 | 21.1 |
| SNE/MA Yellowtail Flounder | 5.7 | 10.1 | 11.5 |

TABLE 15—FISHING YEAR 2016 DEFAULT COMMON POOL TRIMESTER TOTAL ALLOWABLE CATCHES—Continued

[mt, live weight]

| Stock | Trimester 1 | Trimester 2 | Trimester 3 |
|---|---|---|---|
| CC/GOM Yellowtail Flounder | 1.9 | 1.9 | 1.6 |
| American Plaice | 2.2 | 3.3 | 3.7 |
| Witch Flounder | 1.2 | 1.3 | 1.8 |
| Redfish | 4.0 | 5.0 | 7.1 |

**7. Sector Carryover**

Currently, sectors can carry over up to 10 percent of their unused initial allocation into the next fishing year. However, a 2013 court ruling in *Conservation Law Foundation* v. *Pritzker, et al.* (Case No. 1:13–CV–0821–JEB) determined that available sector carryover combined with the total ACL for the upcoming fishing year, or total potential catch, cannot exceed the ABC. As a result, this action specifies that the maximum available carryover may be reduced if up to 10 percent of the unused sector sub-ACL, plus the total ACL for the upcoming fishing year, exceeds the ABC. For example, if 10 percent of sector carryover from the previous year plus the total ACL for the upcoming year was expected to exceed the ABC by 50 mt, then we would reduce the available carryover for each sector. The overall reduction of available carryover would be equal to 50 mt, and this amount would be applied to each sector proportional to the total PSCs of the vessels/permits enrolled in the sector. This measure is intended to reduce the risk of catches exceeding the ABCs that the SSC recommends.

*Sector Carryover From Fishing Year 2014 to 2015*

Based on the catch limits implemented in this action, we evaluated whether the total potential catch in fishing year 2015 would exceed the proposed ABC if sectors carried over the maximum 10 percent of unused allocation allowed from 2014 to 2015 (Table 16). Under this scenario, total potential catch would exceed the 2015 ABC for all groundfish stocks, except for GOM haddock. As a result, we expect we will need to adjust the maximum amount of unused allocation that a sector can carry forward from 2014 to 2015 (down from 10 percent). However, it is possible that not all sectors will have 10 percent of unused allocation at the end of the 2014 fishing year. We will make the final adjustment to the maximum carryover possible for each sector based on final 2014 catch for the sectors, each sector's total unused allocation, and proportional to the cumulative PSCs of vessels/permits participating in the sector. We will announce this adjustment as close to May 1, 2015, as possible.

Based on the catch limits adopted in this final rule, the *de minimis* carryover amount for the 2015 fishing year will be set at the default one percent of the 2015 overall sector sub-ACL. The overall *de minimis* amount will be applied to each sector based on the cumulative PSCs of vessels/permits participating in that sector. If the overall ACL for any allocated stock is exceeded for the 2015 fishing year, the allowed carryover harvested by a sector, minus its specified *de minimis* amount, will be counted against its allocation to determine whether an overage, subject to an AM, occurred.

TABLE 16—EVALUATION OF MAXIMUM CARRYOVER ALLOWED FROM FISHING YEAR 2014 TO 2015

[mt, live weight]

| Stock | 2015 U.S. ABC | 2015 Total ACL | Potential carryover (10% of 2014 sector sub-ACL) | Total potential catch (2015 total ACL + potential carryover) | Difference between total potential catch and ABC |
|---|---|---|---|---|---|
| GB Cod | 1,980 | 1,886 | 174 | 2,060 | 80 |
| GOM cod | 386 | 366 | 81 | 447 | 61 |
| GB Haddock | 24,366 | 23,204 | 1,705 | 24,909 | 543 |
| GOM Haddock | 1,454 | 1,375 | 43 | 1,418 | −36 |
| SNE Yellowtail Flounder | 700 | 666 | 46 | 712 | 12 |
| CC/GOM Yellowtail Flounder | 548 | 524 | 46 | 570 | 22 |
| Plaice | 1,544 | 1,470 | 136 | 1,605 | 61 |
| Witch Flounder | 783 | 751 | 60 | 811 | 28 |
| GB Winter Flounder | 2,010 | 1,952 | 336 | 2,287 | 277 |
| GOM Winter Flounder | 510 | 489 | 68 | 558 | 48 |
| SNE/MA Winter Flounder | 1,676 | 1,607 | 106 | 1,714 | 38 |
| Redfish | 11,974 | 11,393 | 1,052 | 12,445 | 471 |
| White Hake | 4,713 | 4,484 | 425 | 4,909 | 196 |
| Pollock | 16,600 | 15,878 | 1,314 | 17,192 | 592 |

**Note.** Carryover of GB yellowtail flounder is not allowed because this stock is jointly managed with Canada.

**8. 2015 Annual Measures Under Regional Administrator Authority**

The FMP gives us authority to implement certain types of management measures for the common pool fishery, the U.S./Canada Management Area, and Special Management Programs on an annual basis, or as needed. This action implemented a number of these management measures for the 2015 fishing year. These measures are not part of Framework 53, and were not specifically proposed by the Council. We are implementing them in conjunction with Framework 53 measures in this final rule for expediency purposes, and because they

relate to the catch limits proposed in Framework 53.

*Common Pool Trip Limits*

The initial fishing year 2015 days-at-sea (DAS) possession limits and maximum trip limits for common pool vessels are included in Tables 17 and 18. These possession limits were developed after considering changes to the common pool catch limits, catch rates of each stock during 2014, and other available information. During the fishing year, we will adjust possession and trip limits, as necessary, to prevent common pool catch limits from being exceeded.

TABLE 17—INITIAL FISHING YEAR 2015 COMMON POOL POSSESSION AND TRIP LIMITS

| Stock | Possession and trip limits |
|---|---|
| GB Cod (outside Eastern U.S./Canada Area) | 2,000 lb (907 kg) per DAS, up to 20,000 lb (9,072 kg) per trip. |
| GB Cod (inside Eastern U.S./Canada Area) | 100 lb (45 kg) per DAS, up to 500 lb (227 kg) per trip. |
| GOM Cod | 50 lb (23 kg) per DAS, up to 200 lb (91 kg) per trip. |
| GB Haddock | 25,000 lb (11,340 kg) per trip. |
| GOM Haddock | 50 lb (23 kg) per DAS, up to 200 lb (91 kg) per trip. |
| GB Yellowtail Flounder | 100 lb (45 kg) per trip. |
| SNE/MA Yellowtail Flounder | 2,000 lb (907 kg) per DAS, up to 6,000 lb (2,722 kg) per trip. |
| CC/GOM Yellowtail Flounder | 1,500 lb (680 kg) per DAS up to 3,000 lb (1,361 kg) per trip. |
| American plaice | Unlimited. |
| Witch Flounder | 1,000 lb (454 kg) per trip. |
| GB Winter Flounder | 1,000 lb (454 kg) per trip. |
| GOM Winter Flounder | 1,000 lb (454 kg) per trip. |
| SNE/MA Winter Flounder | 3,000 lb (1,361 kg) per DAS, up to 6,000 lb (2,722 kg) per trip. |
| Redfish | Unlimited. |
| White hake | 1,500 lb (680 kg) per trip. |
| Pollock | 10,000 lb (4,536 kg) per trip. |
| Atlantic Halibut | 1 fish per trip. |
| Windowpane Flounder | Possession Prohibited. |
| Ocean Pout | Possession Prohibited. |
| Atlantic Wolffish | Possession Prohibited. |

TABLE 18—INITIAL FISHING YEAR 2015 COD TRIP LIMITS FOR HANDGEAR A, HANDGEAR B, AND SMALL VESSEL CATEGORY PERMITS

| Permit/Stock | Trip limit |
|---|---|
| Handgear A—GOM Cod | 50 lb (23 kg) per trip. |
| Handgear A—GB Cod | 300 lb (136 kg) per trip. |
| Handgear B—GOM Cod | 25 lb (11 kg) per trip. |
| Handgear B—GB Cod | 75 lb (34 kg) per trip. |
| Small Vessel Category | 300 lb (136 kg) of cod, haddock, and yellowtail flounder combined; maximum of 50 lb (23 kg) of GOM cod and 50 lb (23 kg) of GOM haddock within the 300-lb (136-kg) combined trip limit. |

*Closed Area II Yellowtail Flounder/Haddock Special Access Program*

This action allocates zero trips for common pool vessels to target yellowtail flounder within the Closed Area II Yellowtail Flounder/Haddock Special Access Program (SAP) for fishing year 2015. Vessels could still fish in this SAP in 2015 to target haddock, but must fish with a haddock separator trawl, a Ruhle trawl, or hook gear. Vessels will not be allowed to fish in this SAP using flounder nets. This SAP is open from August 1, 2015, through January 31, 2016.

We have the authority to determine the allocation of the total number of trips into the Closed Area II Yellowtail Flounder/Haddock SAP based on several criteria, including the GB yellowtail flounder catch limit and the amount of GB yellowtail flounder caught outside of the SAP. The FMP specifies that no trips should be allocated to the Closed Area II Yellowtail Flounder/Haddock SAP if the available GB yellowtail flounder catch is insufficient to support at least 150 trips with a 15,000-lb (6,804-kg) trip limit (or 2,250,000 lb (1,020,600 kg)). This calculation accounts for the projected catch from the area outside the SAP. Based on the proposed fishing year 2015 GB yellowtail flounder groundfish sub-ACL of 429,240 lb (194,700 kg), there is insufficient GB yellowtail flounder to allocate any trips to the SAP, even if the projected catch from outside the SAP area is zero. Further, given the low GB yellowtail flounder catch limit, catch rates outside of this SAP are more than adequate to fully harvest the 2015 GB yellowtail flounder allocation.

**9. Fishing Year 2015 Northern Windowpane Flounder Accountability Measure**

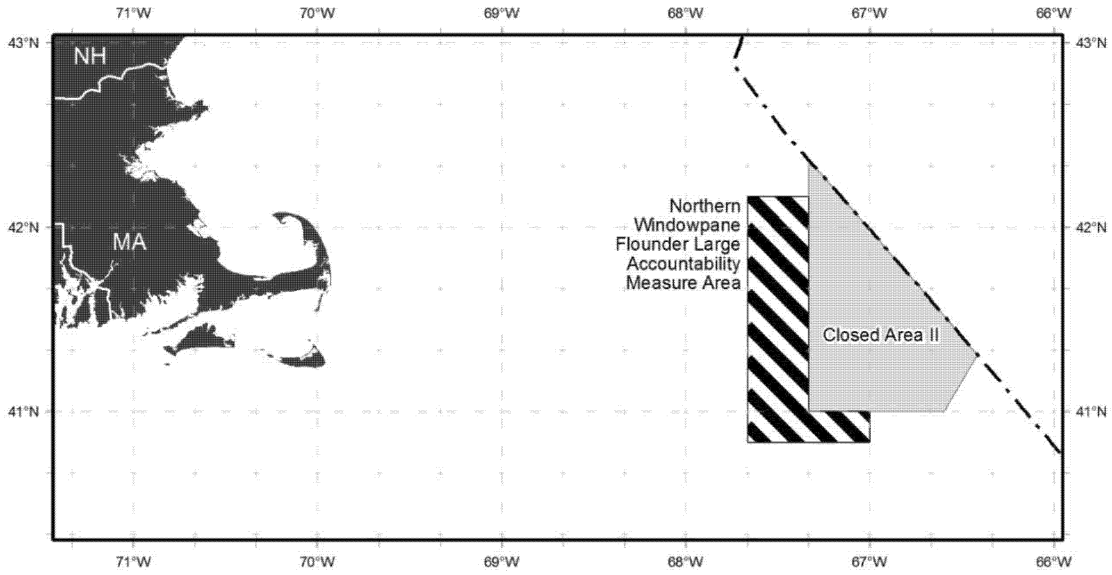
For data reported through April 14, 2015, estimated catch of northern windowpane flounder is 239 mt, which is 166 percent of the total ACL (144 mt) and 118 percent of the OFL (202 mt). Of this estimated catch, the commercial groundfish fishery has caught 156 mt, and the scallop fishery has caught 83 mt. This catch estimate does not include catch from any other non-groundfish fisheries because inseason catch information is not available. However, catch from these components is typically very low.

We are required to implement an AM for northern windowpane flounder in the year immediately following an overage if reliable data indicate that the total ACL has been exceeded. As a result, this final rule implements an AM for northern windowpane flounder for

fishing year 2015 based on the most recent catch information for 2014. For fishing year 2015, common pool and sector vessels fishing on a groundfish trip with trawl gear are required to use one of the approved selective gears when fishing in the applicable AM area (haddock separator trawl, Ruhle trawl, or rope separator trawl). Because the overage is more than 20 percent, the large gear restricted area is implemented for fishing year 2015 (Figure 2). There are no restrictions on common pool or sector vessels fishing with longline or gillnet gear. In addition, the AM will not affect any non-groundfish vessels because northern windowpane is not allocated to any non-groundfish fishery (*e.g.,* scallop fishery).

An overview of the windowpane AM can be found here: *http://www.nero.noaa.gov/sfd/sfdmulti.html*. As a reminder, sectors cannot request an exemption from this AM. The AM will remain in place for the entire 2015 fishing year, unless modified through a future action. As long as additional overages do not occur, the AM will be removed at the start of the 2016 fishing year, beginning on May 1, 2016.

**Figure 2. Northern Windowpane Flounder Accountability Measure Area**




**10. Daily Catch Reporting for Commercial Groundfish Vessels**

In the proposed rule, we highlighted our concern that the low GOM cod catch limit could provide a strong incentive to misreport or underreport catch on unobserved trips. Currently, commercial groundfish vessels that declare their intent to fish in multiple broad stock areas are required to submit trip-level catch reports via the VMS. However, in the proposed rule, we noted that requiring daily VMS catch reports was one potential tool that could help address our concerns for misreporting. After further consideration, and based on public comments we received, we are, through this final rule, requiring vessels to submit a daily VMS catch report on trips declared into the GOM Broad Stock Area and any other broad stock area (*i.e.,* offshore GB or SNE) on the same trip. This reporting requirement is effective on May 1, 2015.

In Amendment 16 to the FMP, the Council recommended requiring daily VMS catch reports for vessels that declare their intent to fish in multiple broad stock areas. Amendment 16 also gave NMFS the discretionary authority to modify this reporting requirement, as we determined was necessary to appropriately monitor the ACLs, while also reducing unnecessary duplication. At the time we implemented Amendment 16, we determined that only trip-level catch reports were necessary for vessels that declared their intent to fish in multiple broad stock areas, and we implemented this requirement beginning for the 2010 fishing year.

In light of the GOM cod catch limit, we determined that daily VMS catch reports for trips declared into the GOM and other broad stock areas on the same trip will help ensure more accurate apportionment of cod catch to the GOM and GB stock areas, help enforcement efforts, and more effectively control mortality on the GOM cod stock. We also expect that the daily VMS catch report may promote more accurate VMS trip declarations because only vessels with a true intent of fishing in the GOM will declare into this area given the daily reporting requirement.

Vessels subject to the daily VMS catch report requirement are not required to also submit a trip-level catch report. The same information currently required for trip-level catch reports will be required for the daily catch reports, namely a good-faith estimate of the amount of each regulated groundfish species retained (in pounds, landed weight) and the total amount of all species retained (in pounds, landed weight), including groundfish species and species managed by other FMPs, from each broad stock area. For applicable trips, daily VMS catch reports must be submitted for each calendar day of the trip (midnight to midnight), and must be submitted by 0900 hr of the following day.

The requirement to submit a daily VMS catch report does not apply to vessels that declare their intent to fish in multiple broad stock areas, but not the GOM. These vessels are still only required to submit a trip-level catch report. For example, if a vessel declares into the offshore GB and SNE/MA Broad Stock Areas, it would only be subject to a trip-level report. This is intended to prevent unnecessary duplication. Most

of our current concerns for catch attribution and compliance are in light of the GOM cod catch limit, and for trips fishing in both the GOM and GB broad stock areas. As a result, we determined that requiring a daily VMS catch report for vessels declared into multiple areas, but not into the GOM, was not necessary at this time.

**11. Regulatory Corrections Under Regional Administrator Authority**

The following changes to the regulations are being made to correct references, inadvertent deletions, and other minor errors.

In § 648.14(k)(7), the reference to the GOM Cod Spawning Protection Area (Whaleback) is corrected. This change was overlooked in a previous management action.

In § 648.14(k)(12) and (13), the introductory text is revised to clarify that the general restrictions listed in these paragraphs apply to any person.

In § 648.87(b)(1)(i)(C)(2), the reference to the sector AM provision is corrected.

In § 648.89(f)(1), the reference to special provisions for recreational catch evaluation for fishing years 2010 and 2011 are removed. These provisions are no longer relevant.

In § 648.90(a)(2)(i), the reference to a special provision for the biennial review for 2008 and 2009 is removed. This provision is no longer relevant.

In § 648.90(a)(2)(viii), a reference is corrected that was overlooked during the implementation of a previous FMP action.

In § 648.90(a)(5)(i), this rule corrects a spelling error.

**Comments and Responses on Measures Proposed in the Framework 53 Proposed Rule**

We received 48 comments during the comment period on the Framework 53 proposed rule. Public comments were submitted by the Council, 2 state marine fisheries agencies, 5 commercial fishing organizations, 1 groundfish sector, 7 commercial fishermen, 1 recreational fishing organization, 24 recreational fishermen, 4 non-governmental organizations (NGOs), and 3 individuals. We requested specific comment on several measures proposed in Framework 53, including some aspects of the GOM cod catch limit and the GOM cod protection measures. Responses to the comments received are below, and, when possible, responses to similar comments on the proposed measures have been consolidated.

*Status Determination Criteria*

*Comment 1:* Two state marine fisheries agencies supported the revised status determination criteria.

*Response:* We agree, and are implementing these changes in this final rule. The revised status determination criteria for GB yellowtail flounder, as well as the updated numerical estimates of the status determination criteria for other groundfish stocks, incorporate the results of the 2014 assessments for these stocks. As a result, these revisions are based on the best scientific information available, and will help ensure the appropriate catch limits are set for these stocks.

*Fishing Year 2015 U.S./Canada Quotas*

*Comment 2:* One state marine fisheries agency supported the fishing year 2015 shared U.S./Canada quotas for eastern GB cod, eastern GB haddock, and GB yellowtail flounder.

*Response:* We agree, and this final rule implements these quotas for fishing year 2015. The 2015 shared U.S./Canada quotas are based on the results of the 2014 Transboundary Resources Assessment Committee assessment, which represents the best scientific information available. These quotas are also consistent with the recommendations of the TMGC and the SSC.

*Fishing Year 2015–2017 Catch Limits (Excluding Gulf of Maine Cod)*

*Comment 3:* Two state marine fisheries agencies, one commercial fishing organization, two recreational fishermen, and one individual supported the fishing years 2015–2017 catch limits for groundfish stocks. One recreational fisherman reported catching much less GOM winter flounder in recent years.

*Response:* We agree, and are implementing these catch limits for fishing years 2015–2017. These catch limits are based on the 2014 assessments for these stocks, which represent the best scientific information available, and are consistent with the SSC's recommendations and conservation objectives. Assessment updates are scheduled for 2015 for all of these stocks, which will provide the opportunity to update the catch limits implemented in this final rule for fishing year 2016 and beyond.

The results of the 2014 assessment update for GOM winter flounder show large declines in the survey indices in recent years. Based on the assessment, the GOM winter flounder catch limits in this action are a 50-percent reduction compared to 2014. This appears to corroborate the commenter's observation of catching much less GOM winter flounder in recent years. The assessment peer review panel expressed concerns that recent biomass estimates substantially decreased despite relatively low catch, and reasons for this apparent decline are not known. Available catch information indicates that the majority of GOM winter flounder catch comes from the same statistical areas as the majority of the GOM cod catch. As a result, the substantial reduction in the GOM cod catch limit is expected to affect catch of GOM winter flounder.

*Comment 4:* One commercial fishing organization, one groundfish sector, and one commercial fisherman opposed the catch limits for GB winter flounder, and noted that the catch limits are overly restrictive. The commercial fishing organization also commented that the Council adopted a 7-year rebuilding program for GB winter flounder with the intention of extending it to 10 years, if necessary, and that a 7-year trajectory is unnecessarily restrictive. The groundfish sector commented that the large reduction will have a negative economic impact on New Bedford.

*Response:* We recognize that the reduction in the catch limit for GB winter flounder may be restrictive for groundfish vessels, particularly in light of other substantial reductions for key groundfish stocks that have been implemented in recent years. The economic impacts analysis for this action predicts that GB winter flounder will generate the third most revenue of all groundfish stocks for fishing year 2015 (following GB haddock and pollock, respectively), and that the groundfish fishery will fully utilize its available GB winter flounder quota. Although not fully captured in the economic analysis, selective gear requirements for northern windowpane flounder may reduce profitability for groundfish vessels targeting GB winter flounder. However, the catch limits are based on the 2014 assessment update for this stock, which is the best scientific information available, and are consistent with the SSC's recommendation.

Amendment 16 to the FMP adopted a 7-year rebuilding program for GB winter flounder with a 75-percent probability of rebuilding by 2017. This shorter time period and higher probability were adopted to provide additional flexibility in the event stock rebuilding lagged behind the planned rebuilding trajectory. However, it is unclear whether this would be the case for GB winter flounder.

Based on the results of the 2014 assessment, estimated biomass for 2013 is approximately 85 percent of the biomass target. Catch projections also indicate that the stock has a 76-percent probability of rebuilding by 2017 if catches for the next 3 years are set based on $F_{rebuild}$. Thus, it appears this stock is on its planned rebuilding trajectory. The SSC recommended ABCs based on $F_{rebuild}$, and did not note any reason to depart from this approach. Further, although the GB winter flounder rebuilding program was not considered in Framework 53, given the retrospective pattern in the assessment, the PDT noted that the conservative rebuilding approach (higher probability) may be appropriate given the revised lower biomass estimates from the 2014 assessment. In any event, we can only approve or disapprove Framework 53 measures. Because the Council did not consider, or approve, extending the rebuilding timeframe for GB winter flounder in Framework 53, such a change is outside the scope and authority of this action.

*Comment 5:* Although supportive of the GOM haddock catch limits included in this action, one commercial fishing organization noted concerns that strong year classes were down-weighted in the stock assessment, and that GB/GOM stock mixing is largely unaccounted for as well.

*Response:* We acknowledge uncertainties around recent year classes, and the possibility of mixing between the GB and GOM haddock stocks. However, these issues were examined in the 2014 benchmark assessment for GOM haddock. The PDT and SSC also completed a review of haddock stock mixing, and this analysis was reviewed during the 2014 assessment. Based on the examination of these issues, the 2014 assessment appropriately accounted for year class uncertainty and mixing, and the peer review panel concluded this was the best scientific information available.

The results of the 2014 stock assessment for GOM haddock indicate that the 2012 year class is strong. However, the size of this potentially large year class was identified as the largest source of uncertainty in the assessment, primarily because it is based on only two surveys. The final model did constrain recruitment estimates in the last 3 years of the time series. This type of adjustment is intended to offset uncertainties due to the low confidence in the survey observations that are not yet substantiated by fishery-dependent data. Although the 2012 year class appears strong, this estimate is still highly uncertain, and the adjustment helps prevent overly optimistic results that could occur from anomalous survey tows. The assessment did explore sensitivity runs that further down-weighted this year class; however, these sensitivity runs were not used to develop the fishing years 2015–2017 catch limits implemented in this action.

We are closely monitoring stock indicators for GOM haddock to gauge if initial indications of a strong 2012 year class are substantiated. The fall 2014 survey indices have increased relative to 2013, and this is likely a function of the signal from incoming year classes. We expect that the 2015 assessment update for GOM haddock will provide additional information about the absolute size of the 2012 year class. However, recent survey indices appear to support the initial indications of a strong 2012 year class.

While it is true that the assessment model does not account for mixing, this issue was examined during the 2014 benchmark assessment. The assessment examined multiple sources of evidence that indicated the annual percent mixing from GB to GOM is low (less than 0.8 percent), but there is considerable uncertainty regarding the degree of mixing. Both the peer review panel and the SSC noted the significant risk to GOM haddock that could occur if the wrong mixing rate is assumed, and ultimately concluded that additional research is needed to determine the stock movement rates before incorporating mixing into the assessment model.

*Gulf of Maine Cod Assessment*

*Comment 6:* Two commercial fishing organizations opposed the process used for the 2014 assessment update. The commenters noted that the process was not transparent, and that we only secured an ad-hoc peer review of the assessment after it had been completed. One commercial fishing organization noted that Framework 53 was largely intended to address northern windowpane flounder, and that the 2014 assessment for GOM cod disrupted this work.

*Response:* We acknowledge that the 2014 assessment for GOM cod was not scheduled, and that stakeholders did not expect to receive updated stock information. In recent years, both the Council and stakeholders have frequently requested more timely information on stock conditions, as well as advanced notice when we see early indications of changes in stock condition. As a result, we have undertaken a number of efforts to develop a more efficient process for generating information on stock status. In 2014, after examining the most recent survey data for GOM cod, we determined that all major indicators of stock health appeared to have deteriorated since the 2012 assessment. Catch and age data for 2012 and 2013 were also available at the time and used to conduct the 2014 stock assessment update. The intent of undertaking the update was part of our larger effort to provide early indications of changes in stock conditions. Once the preliminary results of the assessment update were clear, we shared the information with the Council, and then sought the Council's assistance to conduct a peer review of the stock assessment.

We recognize that recent AMs for northern windowpane flounder have reduced yield of other groundfish stocks on GB. The Council did consider management measures for northern windowpane flounder in Framework 53, including an allocation of this stock for the scallop fishery. However, the Council ultimately took no action on these measures because, as noted in the Council's analysis, it determined that they would not have sufficiently addressed the goal of increasing catch accountability for individual fishery components. Further, in lieu of any changes in Framework 53, the Council set a 2015 priority to review windowpane flounder management, and, depending on the outcome of that review, the Council may potentially identify revisions to the existing management measures.

*Comment 7:* One commercial fisherman, two recreational fishermen, and two commercial fishing organizations commented that, although GOM cod biomass is low, the 2014 assessment results are too pessimistic. These commenters noted that fishermen are reporting an increase in relative cod catch, and that they are catching more cod in areas not recently known for cod.

*Response:* Throughout the development of Framework 53, we have continued to hear from commercial fishermen that cod catches, while still low, have increased relative to recent years. Analysis from the PDT shows a few signs of high cod tows in the commercial fishery. However, available catch data indicate that catch per unit effort has continued to decline through 2014. These data also show that the spatial re-distribution of cod catch patterns in 2013 and 2014 were primarily the result of a spatial shift in fishing effort. Catch efficiency of cod is greater in the western Gulf of Maine, and, in response to catch limit reductions in fishing year 2013, many vessels shifted effort east as one way to

avoid cod. Catch data indicate that the proportion of GOM cod caught from the western GOM declined coincident with an easterly shift in fishing effort. Although it is difficult to distinguish trends in catch per unit effort from declining catch limits, the available data do not appear to support an increased availability of GOM cod. However, if there has been a recent increase in GOM cod, we expect that this increase would be captured in the trawl surveys, and incorporated into subsequent assessments.

*Comment 8:* One NGO commented that the 2014 assessment update did not take a precautionary approach for estimating recruitment. Another NGO commented on the potential for GOM cod to suffer depensation effects at such low biomass levels.

*Response:* We disagree that the assessment did not take a precautionary approach for estimating recruitment. One term of reference for the peer review panel of the 2014 assessment was to perform short-term catch projections that accounted for recent recruitment. The peer review panel concluded that the recruitment protocol for the 2014 assessment update was consistent with the approved benchmark formulation, which assumes that recruitment success is compromised under current SSB levels. Additionally, for the 2014 assessment, age-1 recruitment was estimated using the geometric mean of the most recent 5 years (2009–2013), as opposed to the most recent 10 years, in further recognition of the lower recruitments in recent years. These catch projections using the 5-year geometric mean were used as the basis for the catch advice for fishing years 2015–2017 that we are implementing in this final rule.

During the 2014 assessment, and the development of this action, there was some discussion on the potential for depensation given the very low biomass for GOM cod. Depensation can be caused by several factors, including reduced recruitment at lower SSB levels, reduced egg production or survival when age structure of the spawning population is truncated, or increased predation. As noted above, the catch projections do include the potential for recruitment to be compromised under certain SSB levels. This adjustment was intended to help account for possible depensation effects. Additionally, the 2014 assessment noted the potential for further declines in biomass and truncation of age-structure to affect future recruitment success, and that catch projections could be optimistic. These uncertainties were considered in the development of catch advice for GOM cod and additional protection measures that are implemented in this final rule, as described elsewhere in this preamble, as well as corresponding measures for sectors that are implemented in the final rule for 2015 and 2016 Sector Operations Plans and Contracts.

*Comment 9:* One commercial fishing organization noted concerns that the stock assessment does not adequately capture the specific geographic stock components for GOM cod.

*Response:* The 2012 benchmark assessment for GOM cod identified multiple topics that warranted further investigation, including cod stock structure. Since the 2012 benchmark assessment, a workshop was held on stock structure of cod in the GOM region, and this workshop concluded that there are three genetic stocks. Although some workshop participants concluded there was sufficient evidence to indicate that the current management units should be revised, the workshop was not able to reach any conclusions on the most appropriate management response. Following this workshop, additional information has become available on cod stock structure, and the Council has also set a 2015 priority to examine how stock structure may affect management.

The peer review panel for the 2014 assessment update discussed all of the available information on cod stock structure, and noted that this issue should be further considered in a benchmark assessment. In providing catch advice for fishing years 2015–2017, the SSC also reiterated the importance of continuing the evaluation of cod stock structure, and that this work should be completed as soon as possible. Although recognizing that there are uncertainties in any stock assessment, we determined that the assessments relied on for this action are the best scientific information available. Cod stock structure, along with other topics identified for the GOM cod assessment, will continue to be examined. However, it should be noted that, currently, the GOM cod assessment scheduled for September 2015 is an operational assessment, and not a benchmark assessment.

*Fishing Years 2015–2017 Gulf of Maine Cod Catch Limits*

*Comment 10:* The Council, two state marine fisheries agencies, and three commercial fishing organizations supported the proposed GOM cod catch limits. Although supportive of the catch limit, one commercial fishing organization disagreed with our interpretation that an ABC of 386 mt was not strictly based on an $F_{rebuild}$ approach. This organization also commented that catch projections used to develop catch advice assumed a catch of 1,470 mt for 2014, and the realized 2014 catch is likely lower than this value.

*Response:* For all of the reasons previously discussed in this preamble, we are implementing an ABC of 386 mt in this final rule. We recognize that there may be disagreements on how to characterize an ABC of 386 mt relative to the various provisions of the ABC control rule. However, based on the best scientific information available, and the SSC's final report, we determined that an ABC of 386 mt is consistent with Magnuson-Stevens Act requirements. Based on updated catch projections, this ABC will end overfishing and will not jeopardize the stock's ability to rebuild by 2024. Further, because no peer review body has been able to conclude that any scenario is more plausible than any other, an ABC of 386 mt appropriately incorporates all of the available catch projections. The updated catch projections show little difference in the future catches and biomass between an ABC of 386 mt and an ABC of 200 mt, in part because catch limits would likely need to be set lower under the 386-mt scenario in the out years of the rebuilding period than those needed under 200 mt.

The PDT did explore the sensitivity of catch projections to the 2014 catch assumption. One sensitivity run was completed that assumed a 2014 catch of 1,000 mt instead of 1,470 mt. This sensitivity analysis indicated that a lower 2014 catch would result in approximately 60 mt more catch in 2015. The PDT did not evaluate the likelihood that catch would be 1,000 mt, however, and this sensitivity analysis was not generated for use in providing 2015 catch advice.

*Comment 11:* The Council and one state marine fisheries agency noted concerns that we highlighted uncertainties and requested specific comments on various aspects of the ABC in the proposed rule, and that this appears to conflict with the SSC process for developing ABC recommendations.

*Response:* We give great weight to the SSC's recommendation. The SSC is charged with providing scientific advice to the Council, including ABC recommendations that will meet Magnuson-Stevens Act requirements. We recognize that the SSC considered its catch advice for GOM cod carefully, and thoroughly reviewed the available information. However, as specified in the Magnuson-Stevens Act, we must ensure that any fishery management

plan is carried out in accordance with the provisions of the Act and the National Standards. In order to make a final determination, and as part of the public rulemaking process, we must carefully examine the available information and seek any clarifications necessary to ensure final measures are consistent with applicable requirements. In doing this, it provides the public additional opportunity to comment on the issues and respond to any concerns that we raise. We must then evaluate all comments that we receive during the proposed rule comment period together with the SSC's deliberations, analysis of the proposed measures, and the best scientific information available. For these reasons, we considered it appropriate to raise our concerns regarding the SSC's recommendation in order to make a final determination on the GOM cod catch limits adopted in this rule.

*Comment 12:* Three NGOs opposed an ABC of 386 mt, and instead supported an ABC of 200 mt. These commenters asserted that an ABC of 386 mt was above the level associated with $F_{rebuild}$, that it would fail to rebuild the stock by the rebuilding plan end date of 2024, and, as a result, was not consistent with National Standard 1, Amendment 16, and § 304(e) of the Magnuson-Stevens Act. These commenters noted concerns about the retrospective pattern in the assessment and the past performance of catch projections.

*Response:* We understand the concerns about GOM cod raised by the commenters, and we noted many of these concerns in the proposed rule. GOM cod stock status is poor and appropriate measures must be implemented to ensure conservation objectives are met. As we highlighted during the development of Framework 53, and in our approval of an ABC of 386 mt, we remain concerned for GOM cod, and are proceeding with the caveat that the ABC for the 2016 and 2017 fishing years must be reevaluated in light of the September 2015 assessment for this stock. The ABC adopted in this action is a complex balance between conservation objectives and other Magnuson-Stevens Act requirements that we must take into account.

The development of the ABC adopted in this action is described earlier in the preamble of this rule, and the proposed rule, and is only briefly summarized again here. During the 2014 assessment update, rebuilding catch trajectories were updated based on the new rebuilding program adopted in Framework 51 to the FMP with an end date of 2024. These rebuilding catch projections assumed a constant F for the remaining 9 years of the rebuilding plan. The PDT initially presented these $F_{rebuild}$ projections completed for the 2014 assessment update to the SSC, as well as an option to set a 200-mt constant catch, which was based on the two projection scenarios that indicated rebuilding was possible. The PDT updated the catch projections with the 200-mt constant ABC option, and these projections indicated the stock would still rebuild by 2024. The SSC recommended this provisional ABC of 200 mt, but noted that it was not consistent with the development of the OFL, which incorporated all three catch projections. As a result, the SSC requested additional information from the PDT to consider incidental catch in its ABC recommendation in order to incorporate all three plausible catch projection scenarios, as well as the control rule provision that specifies the ABC should be based on incidental bycatch if rebuilding cannot occur, even in the absence of fishing mortality.

Updated catch projections indicate that the stock can rebuild by 2024 under an ABC of 386 mt for fishing years 2015–2017. Based on our examination of additional catch projections, we determined there is likely little functional biological difference between 200 mt and 386 mt. This is, in part, because lower catches may be necessary in the out years of the rebuilding program under the 386-mt ABC scenario compared to the 200-mt scenario. Based on the available projections, and analysis of the biological impacts of this action, we determined that an ABC of 386 mt is sufficiently below the OFL to prevent overfishing, and will not jeopardize rebuilding progress.

We recognize the recent changes in the perception of stock status and uncertainties in groundfish catch projections. Multiple analyses have been completed that highlight the past performance of groundfish catch projections, and the SSC considers this information each time it provides catch advice for groundfish stocks. In many instances, a constant catch strategy has been used to help offset these uncertainties, and provide an increasingly larger scientific uncertainty buffer as the projections move further from the terminal year of the assessment. The SSC applied this strategy to GOM cod in its recommendation for fishing years 2015–2017. However, more importantly, in providing its catch advice, the SSC noted that pending the results of the 2015 assessment, it would reconsider its catch advice for fishing year 2016 and beyond.

As we noted earlier in the preamble of this rule, we are approving an ABC of 386 mt with the expectation that the catch limits in this final rule will be reassessed for fishing years 2016 and beyond due to the GOM cod assessment update scheduled for September 2015. When considering all three of the available catch projection scenarios, an ABC of 386 mt was a higher option than other catch outputs, most notably the provisional recommendation of 200 mt. However, the 2015 assessment provides an opportunity to closely monitor the status of this stock in order to make any necessary adjustments to the catch limits adopted in this rule for future fishing years. Our approval of the GOM cod ABC, therefore, is, in effect, only approval for the first year (2015) of the remaining rebuilding time period. As a result, we determined that the uncertainties in projection and concerns for the past performance are mitigated given the pending assessment.

Although the Council could have considered, and recommended, an ABC lower than the SSC's recommendation of 386 mt, a lower ABC would not have mitigated economic impacts consistent with Magnuson-Stevens Act national standards and other requirements. In this case, to ignore an alternative that meets conservation objectives of the Magnuson-Stevens Act, and that could help mitigate some of the substantial economic impacts this action is expected to have, would not be consistent with National Standard 8, and could jeopardize achieving optimum yield for the groundfish fishery.

Further, analysis prepared for this action indicates that a lower GOM cod catch limit may create an economic incentive to misreport catch. This incentive may increase under a 200-mt ABC compared to an ABC of 386 mt. Even a slight increase in misreporting could diminish the benefits of a lower catch limit because of the relatively small biological benefit expected from an ABC as low as 200 mt when compared to 386 mt. We have continued to reiterate the importance of controlling fishing mortality, and agree with commenters that this is necessary to help ensure conservation objectives are met for GOM cod. As a result, along with an ABC of 386 mt, we are also implementing an additional reporting requirement for groundfish vessels to help ensure catch remains within this limit, and have also made adjustments to sector exemptions for fishing year 2015 in light of GOM cod stock status.

*Comment 13:* One NGO commented that the proposed rule and supporting

documents inadequately assess the biological impacts of the ABC (386 mt).

*Response:* We disagree. The final report for the 2014 assessment update, supporting analyses developed by the PDT, Council and SSC deliberations, and the Framework 53 Environmental Assessment provide a thorough examination of the impacts of the ABC implemented in this final rule. The development of a GOM cod ABC occurred over the course of a peer review of the 2014 stock assessment, several PDT meetings, two SSC meetings, two Groundfish Committee meetings, and two Council meetings. All of this information, including summaries of the relevant meetings, is publically available, and all of it was incorporated into the Framework 53 Environmental Assessment, which was made available with the proposed rule for this action.

Further, considering all of the available catch projections, there was a wide range of potential catches and fishing mortality rates examined in the supporting analyses. For example, the 2014 assessment update completed catch projections for various catch alternatives ranging from $F_{rebuild}$ to $F_{MSY}$. Catch projections from the 2014 assessment update also explored the sensitivity of the projections to different recruitment assumptions to better ensure projections reflected the recent lower observed recruitment.

Additionally, during the development of Framework 53, the SSC provisionally recommended an ABC of 200 mt. Although this ABC was not its final recommendation, the available catch projections provide a comparison between an ABC of 200 mt and an ABC of 386 mt. The biological impacts of 386 mt were also analyzed in the Framework 53 Environmental Assessment and catch projections were updated with an ABC of 386 mt. This analysis also compared the biological impacts of 386 mt to No Action. In the No Action alternative, groundfish vessels would have been unable to fish because catch limits would not have been set for a number of stocks. Under this scenario, catches would not be completely eliminated because incidental bycatch would still occur in other non-groundfish fisheries. However, the analysis concluded that there was little difference between these two scenarios (200 mt and 386 mt), and that the future catches and biomass indicated from the catch projections were relatively similar. The commenter offered no specific reasons or evidence that contradicts this analysis.

*Comment 14:* Two individual fishermen, one state marine fisheries agency, and three commercial fishing organizations reiterated concerns for the socio-economic impact of the GOM cod ABC. The state marine fisheries agency suggested that the predicted gross revenue losses are likely severe underestimates, and that the economic impacts analysis incorrectly assumed a fluid quota leasing market.

*Response:* We highlighted similar concerns in the proposed rule, particularly our concern that this final rule will primarily impact small vessels and ports north of Boston (Gloucester, MA, and New Hampshire ports). Some measures are expected to provide marginal economic relief that could increase the viability of the inshore fleet. However, even measures designed to provide additional fishing opportunities will not mitigate all of the substantial economic impacts that are expected from the GOM cod ABC. The economic impacts analysis of this action noted that gross revenue for the groundfish fishery has declined in recent years (from $120 million in fishing year 2011 to $79 million in fishing year 2013). The predicted gross revenue losses for fishing year 2015 (approximately 10 percent) may mask some of the economic impacts to small vessels and ports. However, evaluation of the past performance of the economic model used for analysis suggests that, generally, the predicted gross revenues for a fishing year were relatively close to the realized values. Of course, there are uncertainties in the model, and although the model is intended to capture fishery-wide behavior changes related to catch limit changes, it can over-predict landings under a number of circumstances. With all of this in consideration, the economic impacts analysis concluded that the additional declines forecasted for fishing year 2015 would result in impacts to the entire groundfish fishery even greater than previous GOM cod catch limit reductions.

Reductions in the GOM cod catch limit implemented in previous years resulted in economic losses; however, available information indicates the sector fishery has been able to adapt to some degree. Despite some ability to adapt under previous catch limit reductions, GOM cod was constraining in fishing year 2013. The economic impacts analysis did note that if it becomes difficult for fishermen to avoid GOM cod, the predicted gross revenues could be serious overestimates. Further, although the economic impacts analysis attempts to include the possibility of high GOM cod tows, it does not fully capture these risks. If observed trips encounter unexpected high GOM cod tows, these trips could endanger fishing operations for the entire sector. The quota leasing market, and potential changes in fishing year 2015, were discussed in the full economic impacts analysis, and are not repeated here. However, we recognize the comment that the analysis may not fully capture the current quota leasing market.

*Comment 15:* One NGO commented that the management uncertainty buffer should be increased to account for potential observer bias. Another NGO commented that GOM cod needs realistic buffers, but didn't specifically comment on whether the management uncertainty buffers for GOM cod should be adjusted.

*Response:* Each time catch limits are set, the PDT reviews the management uncertainty buffers used for each fishery component and recommends any necessary adjustments. For Framework 53, the PDT reviewed the current management uncertainty buffers, as well as previous analysis completed in support of Framework 50 to the FMP, which set GOM cod catch limits for fishing years 2013–2015.

Both the PDT and the Council have periodically discussed the possibility of increasing the buffers due to evidence that fishing behavior may differ on observed and unobserved trips, possibly resulting in an underestimate of discards. However, to date the PDT has been unable to estimate the amount of suspected bias of observed trips. Further, the PDT concluded that the direction of the bias can change year to year, for reasons that are unknown. As a result, the PDT has been unable to determine whether any adjustments to the existing buffers would be warranted to address potential bias. The PDT concluded that no new information is available at this time that would warrant any changes to the buffers previously adopted in Framework 50 to the FMP, and recommended no changes to the management uncertainty buffers.

*Comment 16:* Multiple commenters suggested various types of management approaches in light of GOM cod stock status and the fishing year 2015 catch limit. Suggestions included splitting the GOM cod quota into biannual allocations or trimester, implementing dynamic inseason closures for bycatch avoidance, and banning all fishing for, or closing the directed fishing for, GOM cod. One NGO requested that we initiate a Secretarial amendment, and another has submitted a petition for rulemaking under the Administrative Procedure Act to prohibit commercial and recreational fishing for GOM cod and to limit catch to a level consistent with rebuilding requirements.

*Response:* Other than the GOM cod possession restriction for the recreational fishery, none of the measures suggested by commenters were proposed in Framework 53, and so are beyond the scope and authority relating to this action because we can only approve or disapprove measures in a framework. In a future action, the Council could develop any combination of management measures it determines are necessary to meet the goals and objectives of the FMP. Additionally, sectors can voluntarily develop GOM cod avoidance mechanisms at any time. In fact, some sectors have already developed additional restrictions for member vessels to help avoid GOM cod and stay within the available allocation for the 2015 fishing year. Although it is still unclear how commercial groundfish vessels will operate in 2015, we expect that the sector fishery, to the extent possible, will continue to find ways to adapt to the new GOM cod catch limit, and target other groundfish stocks.

With the initial 2013 reductions of the GOM cod catch limits, many groundfish vessels were no longer targeting GOM cod, and instead, used available GOM cod quota to access other stocks. Analysis indicates a dramatic decline in targeted GOM cod trips beginning in the 2013 fishing year. As noted earlier in this rule, with an additional 75-percent reduction in fishing year 2015, it is expected that the incentive for sector vessels to take targeted GOM cod trips is virtually eliminated given the extremely low GOM cod allocations that each sector will receive. We are also setting the GOM cod trip limit for the common pool fishery at 50 lb (23 kg) to reduce the incentive to target GOM cod. The combination of commercial measures, along with a prohibition on possession of GOM cod for the recreational fishery, is expected to, in effect, result in a ''bycatch only'' fishery.

Section 304 of the Magnuson-Stevens Act provides the Secretary of Commerce with the authority to prepare, and implement, a fishery management plan if the Council fails to develop a plan after a reasonable period of time, or fails to submit a plan that meets necessary conservation and management objectives. We have carefully considered the available information, and determined that all of the management measures implemented in this final rule, along with corresponding measures implemented through the final rule for 2015–2016 Sector Operations Plans and Contracts and 2015 recreational measures, will provide sufficient protection for GOM cod to prevent overfishing and contribute to rebuilding consistent with Magnuson-Stevens Act requirements. Further, as already noted, we will continue to work with the Council to ensure that GOM cod management measures are reviewed, or updated, as needed. As a result, a Secretarial amendment, at this time, is unnecessary and unwarranted.

The petition for rulemaking is under consideration, and we will respond to this request consistent with the applicable requirements of the Administrative Procedure Act.

*Comment 17:* Two NGOs, one state marine fisheries agency, and two commercial fishing organizations noted concerns for monitoring the low GOM cod catch limit in fishing year 2015. One NGO commented that calculation of the at-sea monitoring coverage level should be at the level of the individual vessel. The two commercial fishing organizations highlighted the importance of electronic monitoring (EM), and that this may provide a way to improve catch accounting. One organization commented that we should implement a requirement to restrict vessels to fishing in a single broad stock area on a trip. The Council also commented in response to the concerns we raised in the proposed rule, and noted that in Amendment 16 to the FMP, the Council provided us with the authority to implement daily catch reporting at any time we deem it necessary.

*Response:* We agree that adequate monitoring, accounting, and enforcement are essential to help ensure catch limits are effective. A description of at-sea monitoring coverage levels is provided in the final rule for the 2015–2016 Sector Operations Plans and Contracts, and is not repeated here.

We recognize that the low GOM cod catch limit may create an economic incentive to misreport, which could reduce the accuracy of catch apportionment. Although we implemented a single broad stock area requirement in our initial 2014 interim action, this measure can severely restrict some fishing operations, and reduce the ability for groundfish vessels to target healthy groundfish stocks. In our 2014 interim action, we determined that, despite the potential negative economic impacts, the single broad stock area requirement was necessary as a mid-year adjustment for the fishery. The 2014 assessment indicated that, if no action was taken, the measures in place for the 2014 fishing year would have resulted in substantial overfishing. The single broad stock area requirement was intended to help minimize further catch, and ensure the effectiveness of the interim measures. However, a requirement to fish in a single broad stock area is not necessary to ensure the effectiveness of the final measures in this rule. All of the measures in this final rule, including a much lower catch limit, are being implemented at the beginning of the 2015 fishing year, as opposed to a mid-year implementation for the 2014 interim rule. These measures, along with corresponding measures implemented through the final rule for 2015–2016 Sector Operations Plans and Contracts, will provide sufficient protection for GOM cod to prevent overfishing and contribute to rebuilding consistent with Magnuson-Stevens Act requirements.

To address concerns for potential misreporting, we are implementing a daily catch report requirement for vessels fishing in the GOM and other broad stock areas. This requirement is intended to help ensure accurate catch attribution and reduce the incentive for vessels to misreport. As the Council noted in its comment, a daily reporting requirement was recommended by the Council in Amendment 16 to the FMP. Amendment 16 also delegated authority to us to modify the frequency of reporting requirements, as necessary, to help ensure accurate catch accounting. At the time we implemented Amendment 16, we determined that daily reporting was not necessary, and implemented a trip-level reporting requirement for vessels fishing in multiple broad stock areas. However, for reasons described earlier in this rule, we determined daily catch reports are now necessary to help ensure the effectiveness of the measures implemented in this final rule.

We agree that EM has the potential to be an effective monitoring tool in the groundfish fishery, but EM is not yet sufficiently developed at this time. We are currently working to address the challenges to implement EM, including legal requirements and data processing, and are also examining costs associated with EM. We are also working with several groundfish sectors for fishing year 2015 to help address some of the remaining challenges to implement EM. If successful, EM could be fully implemented as a monitoring program for a portion of the groundfish fishery in fishing year 2016.

*Comment 18:* One commercial fishing organization commented that, in considering incidental catch, the SSC has addressed concerns for misreporting. The commenter noted that in trying to balance all of the plausible scenarios from the assessment, incorporating incidental catch information attempted to identify what level of catch may be required to keep

the fishery open without directed cod fishing.

*Response:* We recognize that the SSC considered incidental catch information to help develop its final ABC recommendation. An ABC of 386 mt for GOM cod is a considerable reduction from the incidental catch estimates generated for fishing year 2013 (500–600 mt). Further, as discussed in other sections of this rule, an ACL of 1,470 mt in fishing year 2013 was constraining for groundfish vessels. Available analysis indicates there was a marked decline in directed GOM cod trips beginning in 2013. Although sector vessels were able to adapt to some extent to this first substantial reduction for GOM cod, the additional reduction in fishing year 2015 will be substantially more challenging. Thus, we expect that an ABC of 386 mt will effectively remove the incentive for commercial groundfish vessels to fish for this stock.

Nevertheless, with such a low GOM cod allocation, and in considering the supporting analysis, the economic incentive to misreport could still be high, particularly if groundfish vessels continue to report an uptick in cod availability. As a result, as previously described, we are implementing an additional reporting requirement for commercial groundfish vessels to help ensure accurate catch attribution.

*Gulf of Maine Cod Protection Measures*

Protection Closures

*Comment 19:* One state marine fisheries agency and two commercial fishing organizations supported the GOM cod protection closures. The state marine fisheries agency disagreed with our concerns for April, but noted that it expected we would closely monitor the fishery to understand the consequences of opening April. All of these commenters highlighted the importance of providing GOM cod protections while still affording access to healthy groundfish stocks. One other commercial fishing organization supported all of the closures, but noted concerns for the opening of April closures.

*Response:* We generally agree with all of these comments, and as described earlier in this preamble, we approved the new GOM cod protection measures. There are some biological and economic trade-offs with the addition of winter and May-June closures and removal of April closures. We recognize the importance of providing access to healthy stocks, and support this objective of the cod closures, as long as it does not result in unanticipated consequences. However, we remain concerned for GOM cod stock status, and the potential negative impact on other groundfish stocks as a result of opening April. We will continue to urge the Council to reconsider April closures in light of these concerns.

We agree with the commenters that it is important to monitor the effectiveness of these closures, and we intend to closely monitor any potential effort shifts to help ensure the overall conservation objectives for these measures are met. To the extent possible, these closures should also be reviewed as new information becomes available to help identify any potential adjustments to these closures. We expect additional spawning research may also provide more information on spawning locations for GOM cod that the Council could use in its decision-making process.

*Comment 20:* Two NGOs opposed the GOM cod protection closures and commented that the protection closures should be more expansive. One of these NGOs also commented that the protection closures are inadequate under the Magnuson-Stevens Act because they would fail to end overfishing. One commercial fishing organization noted concerns for the opening of April closures.

*Response:* We share some of the concerns noted by commenters, and we have described these concerns in our approval of the protection closures in this final rule. However, we disagree that the protection closures are inadequate under the Magnuson-Stevens Act. As we described earlier in this rule, updated catch projections indicate that the GOM cod ABC of 386 mt will end overfishing and rebuild the stock. The new protection closures are complementary to this ABC, and are measures in addition to the ACLs and AMs adopted for GOM cod. The additional closures are intended to enhance the effectiveness of these conservation measures by further reducing fishing mortality on spawning aggregations. Any additional benefits realized from the area closures are important, particularly for the benefit of the winter spawning component of GOM cod. While more closures always have the potential for increasing the probability of meeting various conservation objectives, we determined that the closures, along with other management measures adopted for fishing year 2015, are sufficient to prevent overfishing and provide for rebuilding.

The GOM cod protection measures, which include the area closures and the recreational possession restriction, were developed by the Council as a package. In developing these measures, the commercial closures were intended to balance biological and economic objectives resulting from the recommended actions. If the opening of April closures was recommended in isolation, with no additional spring or winter closures, we likely would have disapproved this measure. As stated in the preamble, however, we determined that we could not independently approve or disapprove the recommendations for winter and April without undermining the Council's intent to balancing conservation benefits and impacts on the fishing industry. The addition of winter closures is important because there are currently no protections for this spawning component, and some information suggests that a spawning aggregation is not likely to recover once lost. Despite our concerns for GOM cod with the removal of April closures, there are May and June closures, so the removal of April does not completely eliminate protection of the spring spawning component.

Some of the comments from an NGO noted that the protection closures adopted in this final rule would provide less protection than the status quo in a number of instances. In reviewing and analyzing the impacts of the protection closures, the status quo measures must be put in context for the commercial groundfish fishery. With the adoption of Amendment 16, sector vessels were exempt from a number of the GOM rolling closures because sectors are limited by stock-specific allocations and AMs. As noted in the supporting analysis for this document, although a number of closures are being removed, many of these closures only applied to the common pool fishery, which accounts for less than 2 percent of the fishery. In these instances, the impact of removing the closures is expected to be minimal because the sector fishery is already allowed access to these areas.

Given our concerns for the status of GOM cod, we intend to closely monitor stock indicators and fishery operations. We will continue to work with the Council to ensure that the most appropriate GOM cod protection measures are in place. We expect that the Industry Based Survey for GOM Cod will restart at some point in 2015, and that this survey could provide additional information on cod spawning that the Council could use in the future. Additionally, the protection closures developed and implemented in this action overlap with the Council's Habitat Omnibus Amendment. The Council is working to complete this

Amendment, and we will continue to help the Council in this effort to ensure that the goals and objectives of this Amendment are met.

*Comment 21:* Another commercial fishing organization opposed the closure of block 138 in May because it would restrict haddock and pollock catches, and suggested that this closure should be disapproved, or that only a portion of this block should be closed in May. This organization also commented that true spawning areas can only be identified through acoustic telemetry and passive acoustic monitoring.

*Response:* As described earlier, the objectives of the protection closures were to reduce fishing mortality and protect spawning aggregations for GOM cod while allowing access to healthy groundfish stocks. The protection measures were designed to re-configure the existing GOM rolling closures. Although available information on spawning was used to help develop the protection closures in this final rule, other information was also used to evaluate the potential biological and economic trade-offs associated with the final measures. Block 138 was closed in the previous GOM rolling closures, and based on the available information, no change was recommended for this closure in Framework 53. Because the Council recommended that the entire block 138 be closed in May, we cannot modify this closure in any way, or only partially approve a portion of the closure, and still be consistent with the Council's intent. However, in a future action, the Council could reconsider this closure, and make any modifications, if warranted.

We disagree that spawning areas can only be identified through acoustic telemetry and passive acoustic monitoring. The Framework 53 Environmental Assessment describes the analytical techniques used to identify times and location of spawning for GOM cod. Identification of times and areas of potential spawning was not based on a single source of information. Multiple sources of information and analytical approaches were used to identify and corroborate spawning locations.

The analyses note that the NEFSC and MA Division of Marine Fisheries trawl surveys have narrow seasonal coverage, which limits their applicability to spawning cod. However, the Industry Based Survey for GOM cod was specifically designed to study stock distribution and demographics of cod, and also recorded spawning condition of cod caught. As a result, the peer review of the Industry Based Survey concluded that one of the primary uses of the survey data was to describe spawning activity of GOM cod. The Framework 53 analyses did note some caveats with the use of the ichthyoplankton survey data, particularly due to the time period of this survey. However, these data were determined to be useful because the areas highlighted as potential spawning locations were similar to the areas identified using trawl survey data.

*Comment 22:* One NGO commented that it is generally supportive of time-area management for GOM cod, but cautioned that the final protection measures should be supported by the available data. The NGO also noted that we should commit to review the protection closures at a specific time to help ensure that effort shifts from the final measures does not undermine the effectiveness of these measures, or any measures developed by Take Reduction Teams.

*Response:* We generally agree with this comment. As noted earlier in the preamble of this rule, we have some concerns for the removal of April closures, particularly due to potential effort shifts, and the potential impact on other groundfish stocks. Although the protection measures are subject to review once the GOM cod biomass reaches the biomass threshold, we will continue to urge the Council to reconsider these closures in light of their potential negative impacts on other groundfish stocks, and in light of GOM cod stock status. These closures should also be reviewed as more information becomes available for GOM cod. The 2015 assessment update will provide new information on the status of GOM cod, and we expect additional spawning research will be available in the near future that could help further identify areas important to cod spawning.

Regulations to reduce the potential of serious injury and death of marine mammal species will be in place for the western Gulf of Maine regardless of the GOM cod protection closures. The Harbor Porpoise and Atlantic Right Whale Take Reduction Plans are not predicated on the existence of groundfish closed areas, or the GOM cod protection closures. As a result, it is only necessary to amend these Take Reduction Plans if new information indicates that additional interaction risks to marine mammal species are occurring. The Harbor Porpoise and Atlantic Large Whale Take Reduction Teams meet regularly to monitor the implementation of the final Take Reduction Plans for these species. These teams monitor any changes in the interaction rates and fishing behavior that may result from management actions. Based on this review, the Take Reduction Teams determine if modifications to the Take Reduction Plans are warranted in order to meet the requirements of the Marine Mammal Protection Act and the Endangered Species Act.

*Comment 23:* One commercial fishing organization commented that hook gear should be allowed in the protection closures because it does not interfere with spawning.

*Response:* We disagree that hook gear should be allowed in the protection closures. As we noted in the proposed rule, the available research on GOM cod spawning indicates that fishing on spawning cod may affect spawning activity beyond just the removal of fish. Fishing activity may disrupt spawning signals, and, as a result, can reduce spawning success. Additionally, information indicates that if a spawning aggregation is disrupted by fishing activity, it will scatter and not return. Groundfish vessels fishing with hook gear are capable of interrupting spawning aggregations because they are capable of catching cod. Further, the protection closures are also intended to help reduce fishing mortality for GOM cod, and applying these closures to all commercial groundfish vessels was necessary to help ensure this objective is met. Additionally, it is important to note that Handgear A vessels were afforded similar flexibilities as sector vessels, regardless of whether they are fishing in the common pool or a sector. Handgear A vessels are exempt from both the March and October common pool closures.

As indicated in the response to the next comment, we have similar concerns for the potential for other gear types to disrupt spawning, and would support the Council in reconsidering the fisheries and gears that are allowed to fish in the protection areas.

*Comment 24:* Two commercial fishing organizations and one NGO noted that the list of exempted fisheries allowed into the GOM cod protection closures should be reviewed. One NGO also opposed allowing recreational groundfish vessels into these closure areas.

*Response:* We highlighted similar concerns in the proposed rule relative to the gears that are allowed in these protection closures. Because fishing activity may disrupt spawning success, we noted that there is a potential for these exempted fisheries to diminish the additional spawning protection that the closures are intended to provide. We would support the Council reviewing the fisheries allowed into these protection closures, and, if warranted, to

remove the exception for some of these other fisheries and gears. Alternatively, the Council could also consider including other fisheries and gears for a subset of these protection closures to better protect GOM cod spawning while still providing these fisheries with some flexibility.

As discussed earlier in this rule, the recreational fishery may still fish in these protection closures, similar to the previous GOM rolling closures. Instead, this action implements a prohibition on possession of GOM cod for the recreational fishery to help control fishing mortality of GOM cod for this fishery. The intent of this trade off was to help ensure the recreational fishery continued to have access to healthy groundfish stocks. Because most of the protection closures are inshore, it was expected that recreational vessels would largely not have been able to adjust to these closures due to business operations and safety concerns. Applying these protection closures to the commercial groundfish fishery is an important start to ensuring that spawning aggregations of GOM cod are protected. However, we would support the Council reconsidering whether protection closures, or a subset, should be applied to the recreational fishery.

Recreational Fishery Prohibition on Possession of Gulf of Maine Cod

*Comment 25:* One commercial fishing organization, two NGOs, one state marine fisheries agency, and one recreational fisherman supported a prohibition on possession of GOM cod for the recreational fishery. The recreational fisherman noted that survival rates of recreational released GOM cod are relatively high. Other comments highlighted that outreach is essential to ensure this measure is effective.

*Response:* We agree on all of these points, and have approved this measure in this final rule. Updated catch projections indicated that if no adjustment was made to possession restrictions, recreational catch of GOM cod would have exceeded the recreational allocation by 400 percent. During the development of Framework 53, analysis also indicated that non-compliance in the recreational fishery could be as high as 50 percent. In response to this, we have initiated a number of new recreational outreach efforts to help inform recreational anglers of the existing management measures.

Despite the possession restriction implemented in this final rule, projections indicated that the recreational fishery would still likely exceed its GOM cod allocation unless additional measures are implemented. These projections may overestimate the potential recreational effort in 2015, and, if so, could also overestimate GOM cod catch. However, to help ensure that the recreational fishery does not exceed its allocations, we are implementing additional measures under our discretionary authority in a separate rulemaking.

Available information does indicate that the discard mortality of recreationally caught GOM cod is low. Based on the 2012 benchmark assessment, 70 percent of the GOM cod discards from the recreational fishery were expected to survive. A recently conducted study provides additional information that suggests survival rates of released cod could be higher (85 percent).

*Comment 26:* Eighteen recreational fishermen opposed a prohibition on possession of GOM cod for the recreational fishery. These commenters noted that the recreational fishery has little impact on the GOM cod stock, and that the commercial fishery, particularly draggers, have led to the current GOM cod stock status. Many of these commenters supported a small bag limit for GOM cod, and a few comments supported a bag limit of at least 10 fish. Commenters also expressed concern for the socio-economic impact of this measure.

*Response:* We disagree. Both the recreational and the commercial groundfish fishery receive an allocation of GOM cod. Both fisheries have AMs, and we must implement management measures that will help ensure that each fishery stays within its allocation. Updated catch projections indicate that, even under zero possession, the recreational fishery would still exceed its allocation for GOM cod in fishing year 2015, unless additional measures are implemented. Additionally, catch projections that assumed a status quo bag limit (9 fish) indicated that recreational catch would exceed the 2015 allocation by more than 400 percent.

We understand concerns for the socio-economic impact of zero possession for the recreational fishery. Other measures for the recreational fishery were considered for this action to help protect GOM cod. However, these measures would not have mitigated economic impacts to the recreational fishery compared to zero possession. The GOM cod closures, if applied to the recreational fishery, would likely have had even greater economic impacts on the fishery. These closures are mainly inshore, and recreational vessels may have been unable to move to alternative areas to fish for other groundfish stocks. Analysis indicated that the total steam time to fish further offshore, around the closures, would have exceeded the standard party/charter trip of 4 or 6 hours.

Zero possession will help ensure that fishing mortality by the recreational fishery is reduced for GOM cod, while still ensuring the recreational fishery has access to other healthy groundfish stocks. The Council can review this measure in any future action, and if warranted could implement different management measures for the recreational fishery, as long as they would still meet conservation objectives, and help ensure that the recreational fishery does not exceed its allocation.

*Comment 27:* We received six comments from recreational fishermen about various aspects of recreational management measures for the 2015 fishing year, including opposition to the survival rates current used for the recreational caught GOM cod and haddock, the GOM haddock bag limit, the recreational rulemaking process, and recreational gear requirements.

Response: None of these measures were specifically proposed in Framework 53, and therefore are beyond the scope and authority relating to this action. Although this action implements zero possession of GOM cod for the recreational fishery, we are implementing all other recreational measures, including GOM haddock measures, in a separate rulemaking under our discretionary authority to adjustment recreational measures. These measures are intended to prevent the recreational fishery from exceeding its allocations of GOM cod and GOM haddock for the 2015 fishing year. The issues raised by the commenters will be addressed in our separate rule implementing final recreational measures for fishing year 2015.

*Default Catch Limits*

*Comment 28:* One state marine fisheries agency and one commercial fishing organization supported the mechanism to establish default catch limits in years when a management action is delayed. The commercial fishing organization commented that default catch limits set at 35 percent of the previous year's value would be extremely restrictive for groundfish vessels, but this was better than the alternative of no catch limits.

*Response:* We agree, and are implementing this measure in this final rule. We recognize that default catch limits, if implemented, may be

extremely restrictive for groundfish vessels. Although the 2015 assessment schedule is expected to delay implementation of the management action for fishing year 2016, this measure is not intended to allow lengthy delays in implementation of final measures. Default catch limits are available as a management tool to prevent disruption to the groundfish fishery, but any default specifications time period should not be allowed to languish. To help ensure that management actions are still implemented as quickly as possible, the default specifications time period is only from May 1 through July 31. If default catch limits were allowed to languish beyond this period, the severely restricted catch limits could prevent optimum yield in the fishery.

*Sector Carryover Provision*

*Comment 29:* One state marine fisheries agency supported this change to the carryover provision.

*Response:* We agree and are implementing the revision to the sector carryover provision in this final rule. The measure is necessary to comply with a recent court ruling, and ensure that the total potential catch does not exceed the ABC for any stock.

*Comment 30:* One commercial fishing organization expressed concern that the ever changing rules regarding carryover makes it difficult to stabilize business plans, as does the ability for the carryover amount to change year to year.

*Response:* The revision to the sector carryover provision in this final rule is in response to a recent court ruling, as previously described. We have determined that the carryover provision is now consistent with Magnuson-Stevens Act requirements, and will help ensure that total potential catch does not exceed the ABC for any stock. As a result, we do not anticipate any further modifications of the sector carryover provision, unless the Council chooses to revisit this measure in a future action.

We recognize some of the difficulties that sectors face in trying to plan. To help offset some of the uncertainty, we specified that the default *de minimis* amount is 1 percent of the overall sector sub-ACL for the upcoming fishing year. If it is necessary to change the default *de minimis* amount, we will announce this to sectors as soon as we know the recommended ABCs for the upcoming year. Similarly, once ABC recommendations are known for the upcoming year, we will announce the possibility that the maximum carryover amount may need to be adjusted. We cannot make a final determination on the maximum carryover amount until we have final catch information for sectors; however, the initial determination that assumed a maximum of 10-percent carryover provides sectors with an upper bound. We also expect that the years with the greatest uncertainty will be years in which catch limits are dramatically reduced, as we would most likely have to adjust the maximum carryover allowed in those years.

*Common Pool Management Measures*

*Comment 31:* One state marine fisheries agency supported the common pool trip limits.

*Response:* We agree, and are implementing these initial common pool trip limits for fishing year 2015. We will closely monitor common pool catch, and, if necessary, will make appropriate adjustments to the possession and trip limits for common pool vessels. Each year, it is difficult to predict common pool effort, and there is a possibility that some vessels may drop out of a sector and fish in the common pool for fishing year 2015. If this occurs, we may make adjustments to the trip limits to reflect any increases in the number of common pool vessels that are actively fishing.

*Comment 32:* One commercial fisherman opposed a GOM cod trip limit of 50 lb (23 kg), and instead supported a trip limit of at least 100 lb (45 kg). The commenter noted that a 50-lb (23-kg) trip limit would result in high discards.

*Response:* We disagree that the GOM cod trip limit should be set at 100 lb (45 kg). The trimester TAC for GOM cod is less than 2 mt for each trimester in fishing year 2015. In previous years, when we set the GOM cod trip limit at 100 lb (45 kg), common pool vessels continued to target the stock, and the GOM area was prematurely closed before the end of the trimester. A 50-lb (23-kg) trip limit will help create an incentive to avoid GOM cod. This trip limit will also help provide continued access to other groundfish stocks by helping to prevent a premature closure of the trimester.

*Comment 33:* A number of commercial fishermen commented on common pool management measures. Comments included opposition to the current trimester TAC system used for the common pool, the trimester TACs should be divided among trimesters based on recent landings, and that the common pool fishery should receive 10 percent carryover similar to sectors.

*Response:* None of these measures were considered in Framework 53, and they are beyond the scope and authority relating to this action. Any changes to the existing common pool management measures would have to be developed through the Council process in a future management action. The Council could reconsider common pool management measures at any time provided these measures still met the necessary conservation requirements. For example, the trimester TAC AM system is only one type of reactive AM that the Council may use for the common pool fishery.

The allocation of the common pool sub-ACL was developed as part of Amendment 16, and was based on landings through fishing year 2009. These distributions have been unchanged since the implementation of Amendment 16. However the Council can adjust the trimester TAC distribution in a framework action based on landings from the most recent 5 years. Again, any changes to the trimester TAC provision would have to be developed through the Council in a future management action.

*National Environmental Policy Act and Associated Analyses*

*Comment 34:* One NGO commented that Framework 53 does not meet the requirements of the National Environmental Policy Act (NEPA) because it failed to include a reasonable range of alternatives for the GOM cod protection closures. The commenter noted that Framework 53 should have included the 2014 interim closures as one alternative, as well as an additional alternative that was developed by the PDT.

*Response:* We disagree that this action does not meet the requirements of NEPA. Any comments about the sufficiency of the NEPA analysis of this framework must be considered in the context of the ongoing set of measures that adapt to changing conditions and information affecting the overall FMP, and the many different alternatives that have been analyzed over the years. Within this context, Framework 53 does include a reasonable range of alternatives for the GOM cod area closures that represented various combinations of closures based on the available information. The Purpose and Need of Framework 53 related to the area closures was to enhance spawning protection for GOM cod, help reduce fishing mortality of GOM cod, and to minimize the economic impact of the closures by providing access to healthy groundfish stocks.

Although some of the area closures implemented in our 2014 interim action for GOM cod were intended to protect spawning aggregations, area closures were also used as a mechanism to reduce overfishing in lieu of reducing

the catch limit inseason. As a result, it was apparent that the 2014 interim closures would not have met the Purpose and Need of Framework 53 to provide access to healthy groundfish stocks because the interim closures were not designed, or intended, to meet this objective. Further, because the interim closures were designed to reduce overfishing in lieu of an ACL reduction, these closures would have been overly restrictive for fishing year 2015 once the GOM cod catch limit was reduced based on the 2014 assessment result.

The PDT option that the commenter referenced closely resembled the 2014 interim action closures, and in some cases, was more restrictive than the interim closures. Because the protection closures are complementary to the GOM cod catch limit, the option presented by the PDT would likely have been overly restrictive. Further, this option would have virtually shut down the inshore GOM to the groundfish fishery for eight months of the year, and small inshore vessels would likely have been unable to adapt to these closures. Therefore, although the PDT presented this option to the Council's Groundfish Oversight Committee, the Committee did not advance this option for consideration in Framework 53 because it clearly would not have met all of the goals and objectives of the action.

**Changes From the Proposed Rule**

We made one change from the proposed rule in this action. After further consideration of the available information and public comments, we are implementing a daily VMS catch report requirement for commercial groundfish vessels that declare their intent to fish in the GOM and any other broad stock area on the same trip. Given concerns for the low GOM cod catch limit and the potential incentive to misreport, we determined that daily VMS catch reports will help ensure more accurate catch apportionment and compliance with the cod catch limits.

**Classification**

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that the management measures implemented in this final rule are necessary for the conservation and management of the Northeast groundfish fishery and consistent with the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be significant for purposes of Executive Order (E.O.) 12866.

This final rule does not contain policies with Federalism or ''takings'' implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

The Assistant Administrator for Fisheries finds good cause, under authority contained in 5 U.S.C. 553(d)(3), to waive the 30-day delayed effectiveness of this action. The effective date of this action affects a parallel rulemaking approving sector operations plans for the start of the 2015 fishing year on May 1, 2015. In addition, this action sets fishing year 2015 catch limits for several groundfish stocks, revises GOM cod management measures to provide additional protection for the stock, and adopts other measures to improve the management of the groundfish fishery. This final rule must be in effect at the beginning of 2015 fishing year to fully capture the conservation and economic benefits of Framework 53 measures and the 2015 sector operations plans.

During the development of the Framework 53, updated stock information for GOM cod became available. As a result of this updated stock information, the Council had to include additional measures in Framework 53 to respond to this information and increase protection for GOM cod given its poor status. As a result, this rulemaking could not be completed further before this date. Therefore, in order to have this action effective at the beginning of the 2015 fishing year, which begins on May 1, 2015, it is necessary to waive the 30-day delayed effectiveness of this rule.

Failure to waive the 30-day delayed effectiveness would result in no catch limits being specified for a number of groundfish stocks. Without an allocation for these groundfish stocks, sector vessels would be unable to fish beginning on May 1, 2015. This would severely disrupt the fishery, and could result in foregone yield and revenue reductions. The groundfish fishery already faced substantial cuts in the catch limits for many key groundfish stocks beginning in 2013, and this final rule implements additional catch limit reductions. However, if sector vessels were unable to fish beginning on May 1, 2015, the negative economic impacts would exceed any negative economic impacts anticipated from this action. Any further disruption to the fishery that would result from a delay of this final rule could worsen the severe economic impacts to the groundfish fishery. This action includes specifications that would increase the catch limit for haddock, and re-configures GOM closed areas to increase fishing opportunities on healthy groundfish stocks. These measures are intended to help mitigate the economic impacts of the reductions in catch limits for several key groundfish stocks. A delay in implementation of this action would greatly diminish any benefits of these specifications and other approved measures. For these reasons, a 30-day delay in the effectiveness of this rule is impracticable and contrary to the public interest.

**Final Regulatory Flexibility Analysis**

Section 604 of the RFA, 5 U.S.C. 604, requires Federal agencies to prepare a Final Regulatory Flexibility Analysis (FRFA) for each final rule. The FRFA describes the economic impact of this action on small entities. The FRFA includes a summary of significant issues raised by public comments, the analyses contained in Framework 53 and its accompanying Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (IRFA), the IRFA summary in the proposed rule, as well as the summary provided below. A description of the action, why it is being considered, and the legal basis for this action are contained in Framework 53 and in the preamble to the proposed rule, as well as this final rule, and are not repeated here. A copy of the full analysis is available from the NMFS (see **ADDRESSES**).

**A Summary of the Significant Issues Raised by the Public in Response to the IRFA, a Summary of the Agency's Assessment of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments**

Our responses to all of the comments received on the proposed rule, including those that raised significant issues with the proposed action, or commented on the economic analyses summarized in the IRFA, can be found in the Comments and Responses section of this rule. As outlined in that section, significant issues were raised by the public with respect to:

- GOM cod catch limits for the 2015–2017 fishing years;
- GOM cod protection closures; and
- The prohibition on possession of GOM cod for recreational fishing vessels.

Comments 14 and 26 discussed the economic impacts of this action. Comment 14 noted that the GOM cod reduction would have severe negative impacts on the commercial groundfish fishery, and one of these commenters suggested that the analysis may have underestimated the predicted gross revenue losses as a result of the GOM cod reduction. Comment 26 highlighted

concerns that the GOM cod possession restriction for the recreational fishery would have severe socio-economic impacts. There were no other comments directly related to the IRFA.

**Description and Estimate of Number of Small Entities to Which the Rule Would Apply**

The Small Business Administration defines a small business as one that is:

- independently owned and operated;
- not dominant in its field of operation;
- has annual receipts that do not exceed—
  - $20.5 million in the case of commercial finfish harvesting entities (NAICS [1] 114111)
  - $5.5 million in the case of commercial shellfish harvesting entities (NAICS 114112)
  - $7.5 million in the case of for-hire fishing entities (NAICS 114119); or
- has fewer than—
  - 500 employees in the case of fish processors
  - 100 employees in the case of fish dealers.

This final rule affects commercial and recreational fish harvesting entities engaged in the groundfish fishery, the small-mesh multispecies and squid fisheries, the midwater trawl herring fishery, and the scallop fishery. Individually-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several different FMPs, even beyond those impacted by the proposed action. Furthermore, multiple-permitted vessels and/or permits may be owned by entities affiliated by stock ownership, common management, identity of interest, contractual relationships, or economic dependency. For the purposes of the RFA analysis, the ownership entities, not the individual vessels, are considered to be the regulated entities.

Ownership entities are defined as those entities with common ownership personnel as listed on the permit application. Only permits with identical ownership personnel are categorized as an ownership entity. For example, if five permits have the same seven persons listed as co-owners on their permit application, those seven persons would form one ownership entity, that hold those five permits. If two of those seven owners also co-own additional vessels, that ownership arrangement would be considered a separate ownership entity for the purpose of this analysis.

On June 1 of each year, ownership entities are identified based on a list of all permits for the most recent complete calendar year. The current ownership data set used for this analysis is based on calendar year 2013 and contains average gross sales associated with those permits for calendar years 2011 through 2013. In addition to classifying a business (ownership entity) as small or large, a business can also be classified by its primary source of revenue. A business is defined as being primarily engaged in fishing for finfish if it obtains greater than 50 percent of its gross sales from sales of finfish. Similarly, a business is defined as being primarily engaged in fishing for shellfish if it obtains greater than 50 percent of its gross sales from sales of shellfish.

A description of the specific permits that are likely to be impacted by this action is provided below, along with a discussion of the impacted businesses, which can include multiple vessels and/or permit types.

*Regulated Commercial Fish Harvesting Entities*

Table 19 describes the total number of commercial business entities potentially affected by the proposed action. As of May 1, 2014, there were 1,386 commercial business entities potentially affected by this action. These entities participate in, or are permitted for, the groundfish, small-mesh multispecies, herring midwater trawl, and scallop fisheries. For the groundfish fishery, this action directly regulates potentially affected entities through catch limits and other management measures designed to achieve the goals and objectives of the FMP. For the non-groundfish fisheries, this action includes allocations for groundfish stocks caught as bycatch in these fisheries. For each of these fisheries, there are AMs that are triggered if their respective allocations are exceeded. As a result, the likelihood of triggering an AM is a function of changes to the ACLs each year.

TABLE 19—COMMERCIAL FISH HARVESTING ENTITIES REGULATED BY THIS FINAL RULE

| Type | Total number | Classified as small businesses |
|---|---|---|
| Primarily finfish | 813 | 813 |
| Primarily shellfish | 573 | 549 |
| Total | 1,386 | 1,362 |

Limited Access Groundfish Fishery

This action will directly impact entities engaged in the limited access groundfish fishery. The limited access groundfish fishery consists of those enrolled in the sector program and those in the common pool. Both sectors and the common pool are subject to catch limits, and AMs that prevent fishing in a respective stock area when the entire catch limit has been caught. Additionally, common pool vessels are subject to DAS restrictions and trip limits. All permit holders are eligible to enroll in the sector program; however, many vessels remain in the common pool because they have low catch histories of groundfish stocks, which translate into low PSCs. Low PSCs would limit a vessel's viability in the sector program. In general, businesses enrolled in the sector program rely more heavily on sales of groundfish species than vessels enrolled in the common pool.

As of May 1, 2014 (beginning of fishing year 2014), there were 1,046 individual limited access permits. Of these, 613 were enrolled in the sector program, and 433 were in the common pool. For fishing year 2013, which is the most recent complete fishing year, 708 of these limited access permits had landings of any species, and 360 of these permits had landings of groundfish species.

Of the 1,046 individual limited access multispecies permits potentially impacted by this action, there are 868 distinct ownership entities. Of these, 855 are categorized as small entities, and 13 are categorized as large entities.

[1] The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.

However, these totals may mask some diversity among the entities. Many, if not most, of these ownership entities maintain diversified harvest portfolios, obtaining gross sales from many fisheries and not dependent on any one. However, not all are equally diversified. This action is most likely to affect those entities that depend most heavily on sales from harvesting groundfish species. There are 114 entities that are groundfish-dependent, all of which are small, and all of which are finfish commercial harvesting businesses. Of these groundfish-dependent entities, 102 have some level of participation in the sector program, and 12 operate exclusively in the common pool.

Limited Access Scallop Fisheries

The limited access scallop fisheries include limited access scallop permits and Limited Access General Category (LAGC) scallop permits. Limited access scallop businesses are subject to a mixture of DAS restrictions and dedicated area trip restrictions. LAGC scallop businesses are able to acquire and trade LAGC scallop quota, and there is an annual cap on quota/landings. The scallop fishery receives an allocation for GB and SNE/MA yellowtail flounder and southern windowpane flounder. If these allocations are exceeded, AMs are implemented in a subsequent fishing year. These AMs close certain areas of high groundfish bycatch to scallop fishery, and the length of the closure depends on the magnitude of the overage.

Of the total commercial business entities potentially affected by this action (1,386), there are 171 scallop fishing entities. The majority of these entities are defined as shellfish businesses (167). However, four of these entities are defined as finfish businesses, all of which are small. Of the total scallop fishing entities, 149 entities are classified as small entities.

Midwater Trawl Fishery

There are four categories of permits for the herring fishery. Three of these permit categories are limited access, and vary based on the allowable herring possession limits and areas fished. The fourth permit category is open access. Although there is a large number of open access permits issued each year, this category is subject to fairly low possession limits for herring, account for a very small amount of the herring landings, and derive relatively little revenue from the fishery. The midwater trawl herring fishery receives an allocation of GOM and GB haddock. Once the entire allocation for either stock has been caught, the directed herring fishery is closed in the respective area for the remainder of the fishing year. Additionally, if the midwater trawl fishery exceeds its allocation, the overage is deducted from its allocation in the following fishing year.

Of the total commercial business entities potentially regulated by this action (1,386), there are 71 herring fishing entities. Of these, 43 entities are defined as finfish businesses, all of which are small. There are 28 entities that are defined as shellfish businesses, and 21 of these are considered small. For the purposes of this analysis, squid is classified as shellfish. Thus, because there is some overlap with the herring and squid fisheries, it is likely that these shellfish entities derive most of their revenues from the squid fishery.

Small-Mesh Fisheries

The small-mesh exempted fishery allows vessels to harvest species in designated areas using mesh sizes smaller than the minimum mesh size required by the Northeast Multispecies FMP. To participate in the small-mesh multispecies (whiting) fishery, vessels must hold either a limited access multispecies permit or an open access multispecies permit. Limited access multispecies permit holders can only target whiting when not fishing under a DAS or a sector trip, and while declared out of the fishery. A description of limited access multispecies permits was provided above. Many of these vessels target both whiting and longfin squid on small-mesh trips and, therefore, most of them also have open access or limited access squid, mackerel, and butterfish permits. As a result, squid, mackerel, and butterfish permits were not handled separately in this analysis.

The small-mesh fisheries receive an allocation of GB yellowtail flounder. If this allocation is exceeded, an AM is triggered for a subsequent fishing year. The AM requires small-mesh vessels to use selective trawl gear when fishing on GB. This gear restriction is only implemented for one year as a result of an overage, and is removed as long as additional overages do not occur.

Of the total commercial harvesting entities potentially affected by this action, there are 570 small-mesh entities. However, this is not necessarily informative because not all of these entities are active in the whiting fishery. Based on the most recent information, 25 of these entities are considered active, with at least 1 lb of whiting landed. Of these entities, 7 are defined as finfish businesses, all of which are small. There are 18 entities that are defined as shellfish businesses, and 17 of these are considered small. Because there is overlap with the whiting and squid fisheries, it is likely that these shellfish entities derive most of their revenues from the squid fishery.

*Regulated Recreational Party/Charter Fishing Entities*

The charter/party permit is an open access groundfish permit that can be requested at any time, with the limitation that a vessel cannot have a limited access groundfish permit and an open access party/charter permit concurrently. There are no qualification criteria for this permit. Charter/party permits are subject to recreational management measures, including minimum fish sizes, possession restrictions, and seasonal closures.

During calendar year 2014, 732 party/charter permits were issued. Of these, 267 party/charter permit holders reported catching and retaining any groundfish species on at least one for-hire trip. In addition, 204 party/charter permit holders reported catching at least one cod in 2014. While all party/charter fishing businesses that catch cod may be affected by the proposed action, the recreational groundfish fishery only receives an allocation for the GOM stock. Of the 204 party/charter businesses that reported to have caught cod, 106 reported catching cod in the GOM.

A 2013 report indicated that, in the northeast United States, the mean gross sales was approximately $27,650 for a charter business and $13,500 for a party boat. Based on the available information, no business approached the $7.5 million large business threshold. Therefore, the 267 potentially regulated party/charter entities are all considered small businesses.

**Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements**

This action contains a change to an information collection requirement, which has been approved by the Office of Management and Budget (OMB) under OMB Control Number 0648–0605: Northeast Multispecies Amendment 16 Data Collection. The revision requires vessels that declare trips into the GOM Broad Stock Area and any other broad stock area (*i.e.,* GB or SNE/MA) on the same trip to submit a daily catch report via VMS. Vessels fishing in multiple broad stock areas are currently required to submit a trip-level VMS catch report, so this change only increases the frequency of submission for certain trips. The daily catch report is estimated to take 15 minutes to complete, and cost $2.08 per submission. Based on trips to

multiple broad stock areas taken during the 2013 fishing year, the average trip length for vessels that fish in multiple broad stock areas on a single trip is 5 days. If vessels take 7 trips per year, the burden estimate for daily trip reports is 8 hours and $73.

Public comment is sought regarding whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS and to OMB (see **ADDRESSES**).

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

**Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes**

The economic impacts of the measures implemented in this action are summarized below and are discussed in more detail in sections 7.4 and 8.11 of the Framework 53 Environmental Assessment. Although small entities are defined based on gross sales of ownership groups, not physical characteristics of the vessel, it is reasonable to assume that larger vessels are more likely to be owned by large entities. The economic impacts of this action are anticipated to result in aggregate gross revenue losses of approximately $4 million in fishing year 2015, compared to predicted revenues for fishing year 2014. However, these losses are expected to be absorbed primarily by small businesses. Some vessel size classes and ports are predicted to have 50- to 80-percent declines in revenues from groundfish, and many vessels may be forced to relocate to Southern New England ports, or stop fishing altogether.

Because predicted losses are expected to primarily affect small businesses, this action has the potential to place small entities at a competitive disadvantage relative to large entities. This is mainly because large entities may have more flexibility to adjust to, and accommodate, the measures. However, as discussed in more detail below, the additional declines in gross revenues expected as a result of this action will pose serious difficulties for all groundfish vessels and their crew.

*Status Determination Criteria*

This action changes the GB yellowtail flounder status, relative to reference points, to unknown. In addition, this action updates the numerical estimates of the status determination criteria for GOM cod, GOM haddock, GOM winter flounder, GB winter flounder, and pollock. These updates result in lower values of MSY. For some of these, the lower values of MSY result in lower ACLs in the short-term, which is expected to have negative economic impacts (*i.e.,* lower net revenues). However, the updates to the status determination criteria are expected to have positive stock benefits by helping to prevent overfishing. Thus, in the long-term, the changes to status determination criteria are expected to result in higher and more sustainable landings when compared to the No Action option. All of the revisions are based on the 2014 assessments for the respective stocks, and are therefore based on the best scientific information available.

Status determination criteria are formulaic based on the results of a stock assessment. As a result, the only other alternative considered for this action was the No Action option, which would not update the status determination criteria for any groundfish stocks based on the 2014 assessments. This option would not incorporate the best scientific information available, and would not be consistent with Magnuson-Stevens Act requirements, and, as a result, was not selected. This option would not have any immediate economic impacts. However if this option resulted in overfishing in the long-term, then it would have severe negative economic impacts for the fisheries affected by this action.

*Annual Catch Limits*

This action sets catch limits for eastern GB cod and haddock, GOM cod, GOM haddock, GB yellowtail flounder, GOM winter flounder, and Pollock, and has the potential to affect groundfish (including small-mesh), midwater trawl, and scallop-dependent small entities.

For the commercial groundfish fishery, the catch limits are expected to result in a 7-percent decrease in gross revenues on groundfish trips, or $6 million, compared to predicted gross revenues for fishing year 2014. However, as described later, the aggregate predicted revenues for 2015 also depend on the other measures adopted in this action. The negative impacts of the approved catch limits are not expected to be uniformly distributed across vessels size classes. Vessels in the 30–50 ft (9–15 m) category are predicted to incur the largest decrease in gross revenues compared to 2014. Based only on the approved catch limits, vessels in this category could incur revenue losses of 33 percent, and aggregate losses are expected to be more as a result of other measures in this action. Larger vessel classes are not expected to be affected as heavily by the catch limits in this action. Based only on the approved catch limits, 50–75-ft (15–23-m) vessels are predicted to incur losses of 16 percent, and the largest vessels (75 ft (23 m) and greater) are predicted to incur losses of 3 percent.

For the scallop, midwater trawl, and small-mesh fisheries, the catch limits implemented in this action include allocations for bycatch of groundfish species that occurs in these fisheries. The GB yellowtail flounder allocation for both the scallop and small-mesh fisheries would be a decrease in 2015 compared to 2014, which could increase the likelihood of triggering AMs. However, based on recent catch performance, AMs for GB yellowtail flounder have never been implemented for these fisheries as a result of an overage. Additionally, based on scallop management measures that are proposed for 2015, it is not expected that scallop effort will increase on GB relative to recent years. Although the reduction for GB yellowtail flounder could have negative economic impacts, these fisheries are not expected to exceed their respective allocations in 2015, and no AMs are expected to be triggered.

For the midwater trawl fishery, the allocations for GOM and GB haddock are both expected to increase in 2015 relative to 2014. However, in fishing year 2013, the AM for GB haddock was triggered. As a result, it is possible that this could occur again in 2015 depending on catch rates of herring and haddock. If the AM for GB haddock is triggered, there could be negative economic impacts that result from foregone herring yield. The magnitude of these negative impacts would depend on how much herring quota remained at the time the AM was implemented, and whether other herring management areas were open for directed herring fishing.

The catch limits are based on the latest stock assessment information, which is considered the best scientific information available, and the

applicable requirements in the FMP and the Magnuson-Stevens Act. The only other possible alternatives to the catch limits implemented in this action that would mitigate negative impacts would be higher catch limits. Alternative, higher catch limits, however, are not permissible under the law because they would not be consistent with the goals and objectives of the FMP, or the Magnuson-Stevens Act, particularly the requirement to prevent overfishing. The Magnuson-Stevens Act, and case law, prevent implementation of measures that conflict with conservation requirements, even if it means negative impacts are not mitigated. The catch limits implemented in this action are the highest allowed given the best scientific information available, the SSC's recommendations, and requirements to end overfishing and rebuild fish stocks. The only other legally available alternatives to the catch limits in this action would be lower limits, which would not mitigate the economic impacts of this action to the fishery.

Under the No Action option, no catch limits would be specified for the U.S./Canada stocks, GB winter flounder, GOM winter flounder, or pollock. In this scenario, sector vessels would be unable to fish in the respective stock areas at the start of the 2015 fishing year if no allocations were specified. This would result in greater negative economic impacts for vessels compared to the proposed action due to lost revenues as a result of being unable to fish. The proposed action is predicted to result in approximately $77 million in gross revenues from groundfish trips. All of this revenue would be lost if no action was taken to specify catch limits. As a result, this alternative was not selected because if would fail to meet the Magnuson-Stevens Act requirements to achieve optimum yield and consider the needs of fishing communities.

*Gulf of Maine Cod Protection Measures*

This action re-configures the GOM rolling closures for commercial vessels and adopts a prohibition on possession of GOM cod for the recreational fishery. For the commercial groundfish fishery, this action is expected to result in less severe negative economic impacts than the approved catch limits alone. Based on predicted leasing practices, the negative economic impacts of the selected alternative are estimated to be greater compared to other alternatives considered that would have adopted additional GOM cod spawning closures. However, the aggregate economic impacts of the spawning closures that were considered for this action, but not adopted, are largely driven by the flow of quota from smaller inshore vessels, which would be unable to fish, to larger offshore vessels. Although analysis indicated that the selected action would have greater negative impacts compared to these other alternatives, the negative impacts to small vessels are masked by the predicted aggregate gross revenues. The approved action would add closures in some months, while removing other closures, largely in the month of April. Removing closures in April was intended to provide vessels access to healthy groundfish stocks. As a result, the approved action is expected to improve the viability of the inshore fleet, and help mitigate the economic impacts of the approved catch limits, compared to other closure alternatives considered in the action that included different time-area combinations, and that would have maintained April closures.

The ability of the approved action to provide increased spawning protection would largely dictate the long-term economic impacts of this action. If the approved action enhances spawning protection, which translates into increased stock rebuilding, then the long-term economic impacts would be positive. However, if the approved action does not enhance spawning protection or translate into increased stock rebuilding, then the long-term economic impacts would be similar to the status quo, or negative.

For the recreational fishery, the prohibition on GOM cod possession is expected to result in short-term negative economic impacts, as it will likely result in some recreational anglers not booking party/charter trips. However, if the prohibition results in a decrease in fishing mortality relative to the status quo, then it could contribute to stock rebuilding. If this occurs, the long-term economic impacts of the prohibition could be positive if demand for party/charter fishing trips increase as the stock rebuilds. Further, in the long-term, the recreational fishery would benefit from the commercial closures discussed above if they successfully enhance spawning protection and increase stock rebuilding.

Adopting a possession restriction for the recreational fishery, in lieu of time and area closures to protect GOM cod, mitigated economic impacts for the recreational fishery to the extent practicable. The GOM cod protection closures that were considered in this action, but not adopted, would likely have had even greater economic impacts on the recreational fishery. These closures are mainly inshore, and analysis indicated that the total steam time to fish further offshore, around the closures, would have exceeded the standard party/charter trip of 4 or 6 hours. As a result, recreational vessels may have been unable to move to alternative areas to fish for other groundfish stocks.

*Default Groundfish Specifications*

This action establishes a mechanism for setting default catch limits in the event a management action is delayed. This is expected to have positive economic benefits, primarily for sector vessels, compared to the No Action option. Sector vessels are not allowed to fish without an allocation, so if no catch limits are specified for the fishing year, there would be severe negative economic impacts to the groundfish fishery. The default groundfish specifications are expected to prevent the situation that would otherwise occur if no action was taken.

*Sector Carryover*

This action modifies the provision that allows sectors to carryover unused allocation from one fishing year into the next fishing year. The economic impacts of the carryover provision are likely minor, and similar to the status quo. In any fishing year, if the maximum available sector carryover is reduced from 10 percent, this could have a negative economic impact. However, the approved action does not modify the AM for sectors that requires any overages, even overages that result from harvesting available carryover, must be paid back. As a result, the approved action is not expected to largely change sector operations compared to the No Action alternative.

**Small Entity Compliance Guide**

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a small entity compliance guide will be sent to all holders of Federal permits issued for the Northeast multispecies fisheries, as well as the scallop and herring fisheries that receive an allocation of some groundfish stocks. In addition, copies of this final rule and guides (*i.e.,* information bulletins) are available from NMFS at

the following Web site: *http://www.greateratlantic.fisheries.noaa.gov/*.

**List of Subjects in 50 CFR Part 648**

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: April 23, 2015.

**Eileen Sobeck,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

For the reasons stated in the preamble, NMFS amends 50 CFR part 648 as follows:

## PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.2:

■ a. Lift the suspension of the definition for ''Gillnet gear capable of catching multispecies'' and revise it; and

■ b. Remove the definition for ''Gillnet gear capable of catching multispecies (for purposes of the interim action)''.

The revision reads as follows:

### § 648.2 Definitions.

* * * * *

*Gillnet gear capable of catching multispecies* means all gillnet gear except pelagic gillnet gear specified at § 648.81(f)(5)(ii) and pelagic gillnet gear that is designed to fish for and is used to fish for or catch tunas, swordfish, and sharks.

* * * * *

### § 648.10 [Amended]

■ 3. In § 648.10, revise paragraph (k)(2) and remove paragraphs (k)(3)(i)(A) and (B).

The revision reads as follows:

### § 648.10 VMS and DAS requirements for vessel owners/operators.

* * * * *

(k) * * *

(2) *Reporting requirements for NE multispecies vessel owners or operators fishing in more than one broad stock area per trip.* Unless otherwise provided in this paragraph (k)(2), the owner or operator of any vessel issued a NE multispecies limited access permit that has declared its intent to fish within multiple NE multispecies broad stock areas, as defined in paragraph (k)(3) of this section, on the same trip must submit a hail report via VMS providing a good-faith estimate of the amount of each regulated species retained (in pounds, landed weight) and the total amount of all species retained (in pounds, landed weight), including NE multispecies and species managed by other FMPs, from each broad stock area. This reporting requirement is in addition to the reporting requirements specified in paragraph (k)(1) of this section and any other reporting requirements specified in this part. The report frequency is detailed in paragraphs (k)(2)(i) and (ii) of this section.

(i) *Vessels declaring into GOM Stock Area and any other stock area.* A vessel declared to fish in the GOM Stock Area, as defined in paragraph (k)(3)(i), and any other stock area defined in (k)(3)(ii) through (iv) of this section, must submit a daily VMS catch report in 24-hr intervals for each day by 0900 hr of the following day. Reports are required even if groundfish species caught that day have not yet been landed.

(ii) *Vessels declaring into multiple broad stock areas not including GOM Stock Area.* A vessel declared into multiple stock areas defined in (k)(3)(ii) through (iv) of this section, not including the GOM Stock Area I defined in (k)(3)(i), must submit a trip-level report via VMS prior to crossing the VMS demarcation line, as defined in § 648.10, upon its return to port following each fishing trip on which regulated species were caught, as instructed by the Regional Administrator.

(iii) The Regional Administrator may adjust the reporting frequency specified in paragraph (k)(2) of this section.

(iv) *Exemptions from broad stock area VMS reporting requirements.* (A) A vessel is exempt from the reporting requirements specified in paragraph (k)(2) of this section if it is fishing in a special management program, as specified in § 648.85, and is required to submit daily VMS catch reports consistent with the requirements of that program.

(B) The Regional Administrator may exempt vessels on a sector trip from the reporting requirements specified in this paragraph (k)(2) if it is determined that such reporting requirements would duplicate those specified in § 648.87(b).

* * * * *

■ 4. In § 648.14:

■ a. Lift the suspension of paragraphs (k)(6)(i)(E), (k)(7)(i)(A) and (B), (k)(12)(v)(E) and (F), (k)(12)(v)(K) and (L), (k)(13)(i)(D)(*1*) through (*4*), (k)(13)(ii)(B) through (D), (k)(13)(ii)(K) through (M), (k)(14)(viii), and (k)(16)(iii)(A) through (F);

■ b. Revise paragraph (k)(6)(i)(E);

■ c. Remove paragraph (k)(6)(i)(H);

■ d. Revise paragraphs (k)(7)(i)(A) and (B);

■ e. Remove paragraphs (k)(7)(i)(H) through (J);

■ f. Revise paragraph (k)(12)(i) introductory text;

■ g. Remove paragraphs (k)(12)(v)(K) through (N);

■ h. Revise paragraph (k)(13)(i) introductory text;

■ i. Remove paragraphs (k)(13)(i)(D)(*5*) and (*6*), (k)(13)(ii)(K) through (P), and (k)(14)(xii);

■ j. Revise paragraphs (k)(16) introductory text and (k)(16)(iii)(A) and (B); and

■ k. Remove paragraphs (k)(16)(iii)(D) through (H).

The revisions read as follows:

### § 648.14 Prohibitions.

* * * * *

(k) * * *

(6) * * *

(i) * * *

(E) Use, set, haul back, fish with, possess on board a vessel, unless stowed and not available for immediate use as defined in § 648.2, or fail to remove, sink gillnet gear and other gillnet gear capable of catching NE multispecies, with the exception of single pelagic gillnets (as described in § 648.81(f)(5)(ii)), in the areas and for the times specified in § 648.80(g)(6)(i) and (ii), except as provided in § 648.80(g)(6)(i) and (ii), and § 648.81(f)(5)(ii), or unless otherwise authorized in writing by the Regional Administrator.

* * * * *

(7) * * *

(i) * * *

(A) Enter, be on a fishing vessel in, or fail to remove gear from the EEZ portion of the areas described in § 648.81(d)(1), (e)(1), (f)(4), and (g)(1), except as provided in § 648.81(d)(2), (e)(2), (f)(5), (g)(2), and (i).

(B) Fish for, harvest, possess, or land regulated species in or from the closed areas specified in § 648.81(a) through (f) and (n), unless otherwise specified in § 648.81(c)(2)(iii), (f)(5)(i), (f)(5)(iv), (f)(5)(viii) and (ix), (i), (n)(2)(i), or as authorized under § 648.85.

* * * * *

(12) * * *

(i) It is unlawful for any person to:

* * * * *

(13) * * *

(i) It is unlawful for any person to:

* * * * *

(16) *Recreational and charter/party requirements.* It is unlawful for the owner or operator of a charter or party boat issued a valid Federal NE multispecies permit, or for a recreational vessel, as applicable, unless otherwise specified in § 648.17, to do any of the following if fishing under the recreational or charter/party regulations:

* * * * *

(iii) * * *

(A) Fail to comply with the applicable restrictions if transiting the GOM Regulated Mesh Area with cod on board that was caught outside the GOM Regulated Mesh Area.

(B) Fail to comply with the requirements specified in § 648.81(f)(5)(v) when fishing in the areas described in § 648.81(d)(1), (e)(1), and (f)(4) during the time periods specified.

* * * * *

■ 5. In § 648.80:

■ a. Lift the suspension of paragraphs (a)(3)(vi), (a)(3)(viii), (a)(4)(iii), (a)(4)(ix), and (g)(6)(i) and (ii);

■ b. Remove paragraphs (a)(3)(viii) and (ix) and (a)(4)(ix) and (x);

■ c. Revise paragraphs (g)(6)(i) and (ii); and

■ d. Remove paragraphs (g)(6)(iii) and (iv).

The revisions read as follows:

**§ 648.80 NE multispecies regulated mesh areas and restrictions on gear and methods of fishing.**

* * * * *

(g) * * *

(6) * * *

(i) *Requirements for gillnet gear capable of catching NE multispecies to reduce harbor porpoise takes.* In addition to the requirements for gillnet fishing identified in this section, all persons owning or operating vessels in the EEZ that fish with sink gillnet gear and other gillnet gear capable of catching NE multispecies, with the exception of single pelagic gillnets (as described in § 648.81(f)(5)(ii)), must comply with the applicable provisions of the Harbor Porpoise Take Reduction Plan found in § 229.33 of this title.

(ii) *Requirements for gillnet gear capable of catching NE multispecies to prevent large whale takes.* In addition to the requirements for gillnet fishing identified in this section, all persons owning or operating vessels in the EEZ that fish with sink gillnet gear and other gillnet gear capable of catching NE multispecies, with the exception of single pelagic gillnets (as described in § 648.81(f)(5)(ii)), must comply with the applicable provisions of the Atlantic Large Whale Take Reduction Plan found in § 229.32 of this title.

* * * * *

■ 6. In § 648.81:

■ a. Lift suspension of paragraphs (d)(1) through (4), (e)(1) and (2), (f)(1) and (2), (g)(1)(i), (o)(1)(iii), (iv) and (viii) through (x), and (o)(2)(iv);

■ b. Revise paragraph (d)(2);

■ c. Remove paragraphs (d)(3) through (6);

■ d. Revise paragraph (e)(2);

■ e. Remove paragraphs (e)(3) and (4);

■ f. Revise paragraph (f);

■ g. Remove paragraph (g)(1)(vii);

■ h. Revise paragraphs (g)(2) introductory text, (g)(2)(i), and (i); and

■ i. Remove paragraph (o).

The revisions read as follows:

**§ 648.81 NE multispecies closed areas and measures to protect EFH.**

* * * * *

(d) * * *

(2) Unless otherwise restricted under the EFH Closure(s) specified in paragraph (h) of this section, paragraph (d)(1) of this section does not apply to persons on fishing vessels or fishing vessels that meet the criteria in paragraphs (f)(5)(ii) through (v) of this section.

* * * * *

(e) * * *

(2) Unless otherwise restricted under paragraph (h) of this section, paragraph (e)(1) of this section does not apply to persons on fishing vessels or fishing vessels that meet the criteria in paragraphs (f)(5)(ii) through (v) of this section consistent with the requirements specified under § 648.80(a)(5).

* * * * *

(f) *GOM Cod Protection Closures.* (1) Unless otherwise allowed in this part, no fishing vessel or person on a fishing vessel may enter, fish in, or be in; and no fishing gear capable of catching NE multispecies may be in, or on board a vessel in GOM Cod Protection Closures I through V as described, and during the times specified, in paragraphs (f)(4)(i) through (v) of this section.

(2) Any vessel subject to a GOM cod protection closure may transit the area, provided it complies with the requirements specified in paragraph (i) of this section.

(3) The New England Fishery Management Council shall review the GOM Cod Protection Closures Areas specified in this section when the spawning stock biomass for GOM cod reaches the minimum biomass threshold specified for the stock (50 percent of $SSB_{MSY}$).

(4) *GOM Cod Protection Closure Areas.* Charts depicting these areas are available from the Regional Administrator upon request.

(i) *GOM Cod Protection Closure I.* From May 1 through May 31, the restrictions specified in paragraphs (f)(1) and (2) of this section apply to GOM Cod Protection Closure I, which is the area bounded by the following coordinates connected in the order stated by straight lines:

GOM COD PROTECTION CLOSURE I

[May 1–May 31]

| Point | N. latitude | W. longitude |
|---|---|---|
| CPCI 1 ..... | 43°30′ N | (1) |
| CPCI 2 ..... | 43°30′ N | 69°30′ W |
| CPCI 3 ..... | 43°00′ N | 69°30′ W |
| CPCI 4 ..... | 43°00′ N | 70°00′ W |
| CPCI 5 ..... | 42°30′ N | 70°00′ W |
| CPCI 6 ..... | 42°30′ N | 70°30′ W |
| CPCI 7 ..... | 42°20′ N | 70°30′ W |
| CPCI 8 ..... | 42°20′ N | (2) (3) |
| CPCI 1 ..... | 43°30′ N | (1) (3) |

[1] The intersection of 43°30′ N latitude and the coastline of Maine.

[2] The intersection of 42°20′ N latitude and the coastline of Massachusetts.

[3] From Point 8 back to Point 1 following the coastline of the United States.

(ii) *GOM Cod Protection Closure II.* From June 1 through June 30, the restrictions specified in paragraphs (f)(1) and (2) of this section apply to GOM Cod Protection Closure II, which is the area bounded by the following coordinates connected in the order stated by straight lines:

GOM COD PROTECTION CLOSURE II

[June 1–June 30]

| Point | N. latitude | W. longitude |
|---|---|---|
| CPCII 1 ..... | (1) | 69°30′ W |
| CPCII 2 ..... | 43°30′ N | 69°30′ W |
| CPCII 3 ..... | 43°30′ N | 70°00′ W |
| CPCII 4 ..... | 42°30′ N | 70°00′ W |
| CPCII 5 ..... | 42°30′ N | 70°30′ W |
| CPCII 6 ..... | 42°20′ N | 70°30′ W |
| CPCII 7 ..... | 42°20′ N | (2) (3) |
| CPCII 8 ..... | 42°30′ N | (4) (3) |
| CPCII 9 ..... | 42°30′ N | 70°30′ W |
| CPCII 10 ..... | 43°00′ N | 70°30′ W |
| CPCII 11 ..... | 43°00′ N | (5) (6) |
| CPCII 1 ..... | (1) | 69°30′ W [6] |

[1] The intersection of 69°30′ W longitude and the coastline of Maine.

[2] The intersection of 42°20′ N latitude and the coastline of Massachusetts.

[3] From Point 7 to Point 8 following the coastline of Massachusetts.

[4] The intersection of 42°30′ N latitude and the coastline of Massachusetts.

[5] The intersection of 43°00′ N latitude and the coastline of New Hampshire.

[6] From Point 11 back to Point 1 following the coastlines of New Hampshire and Maine.

(iii) *GOM Cod Protection Closure III.* From November 1 through January 31, the restrictions specified in paragraphs (f)(1) and (2) of this section apply to GOM Cod Protection Closure III, which is the area bounded by the following coordinates connected in the order stated by straight lines:

GOM COD PROTECTION CLOSURE III

[November 1–January 31]

| Point | N. latitude | W. longitude |
|---|---|---|
| CPCIII 1 | 42°30′ N | (1) |
| CPCIII 2 | 42°30′ N | 70°30′ W |
| CPCIII 3 | 42°15′ N | 70°30′ W |
| CPCIII 4 | 42°15′ N | 70°24′ W |
| CPCIII 5 | 42°00′ N | 70°24′ W |
| CPCIII 6 | 42°00′ N | (2) (3) |
| CPCIII 1 | 42°30′ N | (1) (3) |

[1] The intersection of 42°30′ N latitude and the Massachusetts coastline.

[2] The intersection of 42°00′ N latitude and the mainland Massachusetts coastline at Kingston, MA.

[3] From Point 6 back to Point 1 following the coastline of Massachusetts.

(iv) *GOM Cod Protection Closure IV.* From October 1 through October 31, the restrictions specified in paragraphs (f)(1) and (2) of this section apply to GOM Cod Protection Closure IV, which is the area bounded by the following coordinates connected in the order stated by straight lines:

GOM COD PROTECTION CLOSURE IV

[October 1–October 31]

| Point | N. latitude | W. longitude |
|---|---|---|
| CPCIV 1 | 42°30′ N | (1) |
| CPCIV 2 | 42°30′ N | 70°00′ W |
| CPCIV 3 | 42°00′ N | 70°00′ W |
| CPCIV 4 | 42°00′ N | (2) (3) |
| CPCIV 1 | 42°30′ N | (1) (3) |

[1] The intersection of 42°30′ N latitude and the Massachusetts coastline

[2] The intersection of 42°00′ N latitude and the mainland Massachusetts coastline at Kingston, MA

[3] From Point 4 back to Point 1 following the coastline of Massachusetts

(v) *GOM Cod Protection Closure V.* From March 1 through March 31, the restrictions specified in paragraphs (f)(1) and (2) of this section GOM Cod Protection Closure V, which is the area bounded by the following coordinates connected in the order stated by straight lines:

GOM COD PROTECTION CLOSURE V

[March 1–March 31]

| Point | N. latitude | W. longitude |
|---|---|---|
| CPCV 1 | 42°30′ N | 70°00′ W |
| CPCV 2 | 42°30′ N | 68°30′ W |
| CPCV 3 | 42°00′ N | 68°30′ W |
| CPCV 4 | 42°00′ N | 70°00′ W |
| CPCV 1 | 42°30′ N | 70°00′ W |

(5) The GOM cod protection closures specified in this section do not apply to persons aboard fishing vessels or fishing vessels that meet any of the following criteria:

(i) That have not been issued a multispecies permit and that are fishing exclusively in state waters;

(ii) That are fishing with or using exempted gear as defined under this part, except for pelagic gillnet gear capable of catching NE multispecies, unless fishing with a single pelagic gillnet not longer than 300 ft (91.4 m) and not greater than 6 ft (1.83 m) deep, with a maximum mesh size of 3 inches (7.6 cm), provided that:

(A) The net is attached to the boat and fished in the upper two-thirds of the water column;

(B) The net is marked with the owner's name and vessel identification number;

(C) There is no retention of regulated species; and

(D) There is no other gear on board capable of catching NE multispecies;

(iii) That are fishing in the Midwater Trawl Gear Exempted Fishery as specified in § 648.80(d);

(iv) That are fishing in the Purse Seine Gear Exempted Fishery as specified in § 648.80(e);

(v) That are fishing under charter/party or recreational regulations specified in § 648.89, provided that:

(A) For vessels fishing under charter/party regulations in a GOM cod protection closure described under paragraph (f)(4) of this section, it has on board a letter of authorization issued by the Regional Administrator, which is valid from the date of enrollment through the duration of the closure or 3 months duration, whichever is greater; for vessels fishing under charter/party regulations in the Cashes Ledge Closure Area or Western GOM Area Closure, as described under paragraphs (d) and (e) of this section, respectively, it has on board a letter of authorization issued by the Regional Administrator, which is valid from the date of enrollment until the end of the fishing year;

(B) Fish species managed by the NEFMC or MAFMC that are harvested or possessed by the vessel, are not sold or intended for trade, barter or sale, regardless of where the fish are caught;

(C) The vessel has no gear other than rod and reel or handline on board; and

(D) The vessel does not use any NE multispecies DAS during the entire period for which the letter of authorization is valid;

(vi) That are fishing with or using scallop dredge gear when fishing under a scallop DAS or when lawfully fishing in the Scallop Dredge Fishery Exemption Area as described in § 648.80(a)(11), provided the vessel does not retain any regulated NE multispecies during a trip, or on any part of a trip; or

(vii) That are fishing in the Raised Footrope Trawl Exempted Whiting Fishery, as specified in § 648.80(a)(15), or in the Small Mesh Area II Exemption Area, as specified in § 648.80(a)(9);

(viii) That are fishing on a sector trip, as defined in this part, and in the GOM Cod Protection Closures IV or V, as specified in paragraphs (f)(4)(iv) and (v) of this section; or

(ix) That are fishing under the provisions of a Northeast multispecies Handgear A permit, as specified at § 648.82(b)(6), and in the GOM Cod Protection Closures IV or V, as specified in paragraphs (f)(4)(iv) and (v) of this section .

(g) * * *

(2) Paragraph (g)(1) of this section does not apply to persons on fishing vessels or to fishing vessels that meet any of the following criteria:

(i) That meet the criteria in paragraphs (f)(5)(i), (ii), or (iii) of this section;

* * * * *

(i) *Transiting.* Unless otherwise restricted or specified in this paragraph (i), a vessel may transit CA I, the Nantucket Lightship Closed Area, the Cashes Ledge Closed Area, the Western GOM Closure Area, the GOM Cod Protection Closures, the GB Seasonal Closure Area, the EFH Closure Areas, and the GOM Cod Spawning Protection Area, as defined in paragraphs (a)(1), (c)(1), (d)(1), (e)(1), (f)(4), (g)(1), (h)(1), and (n)(1), of this section, respectively, provided that its gear is stowed and not available for immediate use as defined in § 648.2. A vessel may transit CA II, as defined in paragraph (b)(1) of this section, in accordance with paragraph (b)(2)(iv) of this section. Private recreational or charter/party vessels fishing under the Northeast multispecies provisions specified at § 648.89 may transit the GOM Cod Spawning Protection Area, as defined in paragraph (n)(1) of this section, provided all bait and hooks are removed from fishing rods, and any regulated species on board have been caught outside the GOM Cod Spawning Protection Area and has been gutted and stored.

* * * * *

**§ 648.82 [Amended]**

■ 7. In § 648.82, lift the suspension of paragraphs (b)(5) through (8), and remove paragraphs (b)(7) through (10).

**§ 648.85 [Amended]**

■ 8. In § 648.85, lift the suspension of paragraphs (b)(6)(iv)(D) and (K) and remove paragraphs (b)(6)(iv)(K) and (L).

**§ 648.86 [Amended]**

■ 9. In § 648.86, lift the suspension of paragraphs (b)(1) through (7) and remove paragraphs (b)(5) through (10).

■ 10. In § 648.87:

■ a. Lift the suspension of paragraphs (b)(1)(v)(A), (b)(1)(ix), (b)(1)(x), (c)(2)(i), (c)(2)(ii)(A) and (B), (c)(2)(ii)(E), and (c)(2)(iii);

■ b. Revise paragraphs (b)(1)(i)(C) and (b)(1)(iii)(C);

■ c. Remove paragraphs (b)(1)(v)(C) and (b)(1)(x) and (xi);

■ d. Revise paragraphs (c)(2)(i) and (c)(2)(ii)(B); and

■ e. Remove paragraphs (c)(2)(ii)(E) through (G) and (c)(2)(iii) and (iv).

The revisions read as follows:

**§ 648.87 Sector allocation.**

* * * * *

(b) * * *

(1) * * *

(i) * * *

(C) *Carryover.* (*1*) With the exception of GB yellowtail flounder, a sector may carryover an amount of ACE equal to 10 percent of its original ACE for each stock that is unused at the end of one fishing year into the following fishing year, provided that the total unused sector ACE plus the overall ACL for the following fishing year does not exceed the ABC for the fishing year in which the carryover may be harvested. If this total exceeds the ABC, NMFS shall adjust the maximum amount of unused ACE that a sector may carryover (down from 10 percent) to an amount equal to the ABC of the following fishing year. Any adjustments made would be applied to each sector based on its total unused ACE and proportional to the cumulative PSCs of vessels/permits participating in the sector for the particular fishing year, as described in paragraph (b)(1)(i)(E) of this section.

(*i*) *Eastern GB Stocks Carryover.* Any unused ACE allocated for Eastern GB stocks in accordance with paragraph (b)(1)(i)(B) of this section shall contribute to the carryover allowance for each stock, as specified in this paragraph (b)(1)(i)(C)(*1*), but shall not increase individual sector's allocation of Eastern GB stocks during the following year.

(*ii*) This carryover ACE remains effective during the subsequent fishing year even if vessels that contributed to the sector allocation during the previous fishing year are no longer participating in the same sector for the subsequent fishing year.

(*2*) *Carryover accounting.* (*i*) If the overall ACL for a particular stock is exceeded, the allowed carryover of a particular stock harvested by a sector, minus the NMFS-specified *de minimis* amount, shall be counted against the sector's ACE for purposes of determining an overage subject to the AM in paragraph (b)(1)(iii) of this section.

(*ii*) *De Minimis Carryover Amount.* The *de minimis* carryover amount is one percent of the overall sector sub-ACL for the fishing year in which the carryover would be harvested. NMFS may change this *de minimis* carryover amount for any fishing year through notice consistent with the Administrative Procedure Act. The overall *de minimis* carryover amount would be applied to each sector proportional to the cumulative PSCs of vessels/permits participating in the sector for the particular fishing year, as described in paragraph (b)(1)(i)(E) of this section.

* * * * *

(iii) * * *

(C) *ACE buffer.* At the beginning of each fishing year, NMFS shall withhold 20 percent of a sector's ACE for each stock for a period of up to 61 days (*i.e.,* through June 30), unless otherwise specified by NMFS, to allow time to process any ACE transfers submitted at the end of the fishing year pursuant to paragraph (b)(1)(viii) of this section and to determine whether the ACE allocated to any sector needs to be reduced, or any overage penalties need to be applied to individual permits/vessels in the current fishing year to accommodate an ACE overage by that sector during the previous fishing year, as specified in paragraph (b)(1)(iii) of this section. NMFS shall not withhold 20 percent of a sector's ACE at the beginning of a fishing year in which default specifications are in effect, as specified in § 648.90(a)(3).

* * * * *

(c) * * *

(2) * * *

(i) *Regulations that may not be exempted for sector participants.* The Regional Administrator may not exempt participants in a sector from the following Federal fishing regulations: Specific times and areas within the NE multispecies year-round closure areas; permitting restrictions (*e.g.,* vessel upgrades, etc.); gear restrictions designed to minimize habitat impacts (*e.g.,* roller gear restrictions, etc.); reporting requirements; AMs specified in § 648.90(a)(5)(i)(D). For the purposes of this paragraph (c)(2)(i), the DAS reporting requirements specified in § 648.82; the SAP-specific reporting requirements specified in § 648.85; and the reporting requirements associated with a dockside monitoring program are not considered reporting requirements, and the Regional Administrator may exempt sector participants from these requirements as part of the approval of yearly operations plans. For the purpose of this paragraph (c)(2)(i), the Regional Administrator may not grant sector participants exemptions from the NE multispecies year-round closures areas defined as Essential Fish Habitat Closure Areas as defined in § 648.81(h); the Fippennies Ledge Area as defined in paragraph (c)(2)(i)(A) of this section; Closed Area I and Closed Area II, as defined in § 648.81(a) and (b), respectively, during the period February 16 through April 30; and the Western GOM Closure Area, as defined at § 648.81(e), where it overlaps with GOM Cod Protection Closures I through III, as defined in § 648.81(f)(4). This list may be modified through a framework adjustment, as specified in § 648.90.

* * * * *

(ii) * * *

(B) The GOM Cod Protection Closures IV and V specified in § 648.81(f)(4)(iv) and (v) and the GB Seasonal Closed Area specified in § 648.81(g)(1);

* * * * *

**§ 648.88 [Amended]**

■ 11. In § 648.88, lift the suspension of paragraphs (a)(1) and (3), and remove paragraphs (a)(3) and (4).

■ 12. In § 648.89:

■ a. Lift the suspension of paragraphs (b)(3), (c)(1) and (2), (c)(8), and (e)(1) through (4);

■ b. Revise paragraphs (c)(1) and (c)(2)(i);

■ c.. Remove paragraphs (c)(2)(v) and (c)(8) and (9);

■ c. Revise paragraph (e)(1);

■ d. Remove paragraphs (e)(4) through (7); and

■ e. Revise paragraph (f).

The revisions read as follows:

**§ 648.89 Recreational and charter/party vessel restrictions.**

* * * * *

(c) *Possession Restrictions*—(1) *Recreational fishing vessels.* (i) Each person on a private recreational vessel may possess no more than 10 cod per day in, or harvested from, the EEZ when fishing outside of the GOM Regulated Mesh Area specified in § 648.80(a)(1).

(ii) When fishing in the GOM Regulated Mesh Area specified in § 648.80(a)(1), persons aboard private recreational fishing vessels may not fish for or possess any cod with the exception that private recreational vessels in possession of cod caught outside the GOM Regulated Mesh Area specified in § 648.80(a)(1) may transit this area, provided all bait and hooks

are removed from fishing rods and any cod on board has been gutted and stored.

(iii) For purposes of counting fish, fillets will be converted to whole fish at the place of landing by dividing the number of fillets by two. If fish are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole fish.

(iv) Cod harvested by recreational fishing vessels in or from the EEZ with more than one person aboard may be pooled in one or more containers. Compliance with the possession limit will be determined by dividing the number of fish on board by the number of persons on board. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner or operator of the vessel.

(v) Cod must be stored so as to be readily available for inspection.

(2) *Charter/party vessels.* (i) Persons aboard charter/party fishing vessels permitted under this part and not fishing under the NE multispecies DAS program or on a sector trip that are fishing in the GOM Regulated Mesh Area specified in § 648.80(a)(1) may not fish for, possess, or land any cod with the exception that charter/party vessels in possession of cod caught outside the GOM Regulated Mesh Area specified in § 648.80(a)(1) may transit this area, provided all bait and hooks are removed from fishing rods and any cod on board has been gutted and stored.

* * * * *

(e) * * *

(1) *GOM Closed Areas.* (i) A vessel fishing under charter/party regulations may not fish in the GOM closed areas specified in § 648.81(d)(1), (e)(1), and (f)(4) during the time periods specified in those paragraphs, unless the vessel has on board a valid letter of authorization issued by the Regional Administrator pursuant to § 648.81(f)(5)(v) and paragraph (e)(3) of this section. The conditions and restrictions of the letter of authorization must be complied with for a minimum of 3 months if the vessel fishes or intends to fish in the GOM cod protection closures; or for the rest of the fishing year, beginning with the start of the participation period of the letter of authorization, if the vessel fishes or intends to fish in the year-round GOM closure areas.

(ii) A vessel fishing under charter/party regulations may not fish in the GOM Cod Spawning Protection Area specified at § 648.81(n)(1) during the time period specified in that paragraph, unless the vessel complies with the requirements specified at § 648.81(n)(2)(iii).

* * * * *

(f) *Recreational fishery AM*—(1) *Catch evaluation.* As soon as recreational catch data are available for the entire previous fishing year, the Regional Administrator will evaluate whether recreational catches exceed any of the sub-ACLs specified for the recreational fishery pursuant to § 648.90(a)(4). When evaluating recreational catch, the components of recreational catch that are used shall be the same as those used in the most recent assessment for that particular stock. To determine if any sub-ACL specified for the recreational fishery was exceeded, the Regional Administrator shall compare the 3-year average of recreational catch to the 3-year average of the recreational sub-ACL for each stock.

(2) *Reactive AM adjustment.* (i) If it is determined that any recreational sub-ACL was exceeded, as specified in paragraph (f)(1) of this section, the Regional Administrator, after consultation with the New England Fishery Management Council, shall develop measures necessary to prevent the recreational fishery from exceeding the appropriate sub-ACL in future years. Appropriate AMs for the recreational fishery, including adjustments to fishing season, minimum fish size, or possession limits, may be implemented in a manner consistent with the Administrative Procedure Act, with final measures published in the **Federal Register** no later than January when possible. Separate AMs shall be developed for the private and charter/party components of the recreational fishery.

(ii) The Regional Administrator shall not adjust the possession limit for GOM cod, under the reactive AM authority specified in paragraph (f)(2)(i) of this section, as long as possession of this stock is prohibited for the recreational fishery, as specified in paragraph (c) of this section.

(3) *Proactive AM adjustment.* (i) When necessary, the Regional Administrator, after consultation with the New England Fishery Management Council, may adjust recreational measures to ensure the recreational fishery achieves, but does not exceed any recreational fishery sub-ACL in a future fishing year. Appropriate AMs for the recreational fishery, including adjustments to fishing season, minimum fish size, or possession limits, may be implemented in a manner consistent with the Administrative Procedure Act, with final measures published in the **Federal Register** prior to the start of the fishing year where possible. In specifying these AMs, the Regional Administrator shall take into account the non-binding prioritization of possible measures recommended by the Council: for cod, first increases to minimum fish sizes, then adjustments to seasons, followed by changes to bag limits; and for haddock, first increases to minimum size limits, then changes to bag limits, and then adjustments to seasons.

(ii) The Regional Administrator shall not adjust the possession limit for GOM cod, under the proactive AM authority specified in paragraph (f)(3)(i) of this section, as long as possession of this stock is prohibited for the recreational fishery, as specified in paragraph (c) of this section.

■ 13. In § 648.90, revise paragraphs (a)(2)(i) and (viii), (a)(3), and (a)(5)(i) introductory text to read as follows:

**§ 648.90 NE multispecies assessment, framework procedures and specifications, and flexible area action system.**

* * * * *

(a) * * *

(2) * * *

(i) The NE multispecies PDT shall meet on or before September 30 every other year to perform a review of the fishery, using the most current scientific information available provided primarily from the NEFSC. Data provided by states, ASMFC, the USCG, and other sources may also be considered by the PDT. Based on this review, the PDT will develop ACLs for the upcoming fishing year(s) as described in paragraph (a)(4) of this section and develop options for consideration by the Council if necessary, on any changes, adjustments, or additions to DAS allocations, closed areas, or other measures necessary to rebuild overfished stocks and achieve the FMP goals and objectives.

* * * * *

(viii) If the Regional Administrator concurs in the Council's recommendation, a final rule shall be published in the **Federal Register** on or about April 1 of each year, with the exception noted in paragraph (a)(2)(vii) of this section. If the Council fails to submit a recommendation to the Regional Administrator by February 1 that meets the FMP goals and objectives, the Regional Administrator may publish as a proposed rule one of the options reviewed and not rejected by the Council, provided that the option meets the FMP objectives and is consistent with other applicable law. If, after considering public comment, the Regional Administrator decides to

approve the option published as a proposed rule, the action will be published as a final rule in the **Federal Register**.

* * * * *

(3) *Default OFLs, ABCs, and ACLs.* (i) Unless otherwise specified in this paragraph (a)(3), if final specifications are not published in the **Federal Register** for the start of a fishing year, as outlined in paragraph (a)(4) of this section, specifications for that fishing year shall be set at 35 percent of the previous year's specifications for each NE multispecies stock, including the U.S./Canada shared resources, for the period of time beginning on May 1 and ending on July 31, unless superseded by the final rule implementing the current year's specifications.

(ii) If the default specifications exceed the Council's recommendations for any stock for the current year, the specifications for that stock shall be reduced to the Council's recommendation through notice consistent with the Administrative Procedure Act.

(iii) These specifications shall be subdivided among the various sub-components of the fishery consistent with the ABC/ACL distribution adopted for the previous year's specifications.

* * * * *

(5) * * *

(i) *AMs for the NE multispecies commercial and recreational fisheries.* If the catch of regulated species or ocean pout by a sub-component of the NE multispecies fishery (*i.e.,* common pool vessels, sector vessels, or private recreational and charter/party vessels) exceeds the amount allocated to each sub-component, as specified in paragraph (a)(4)(iii)(H) of this section, then the applicable AM for that sub-component of the fishery shall take effect, pursuant to paragraphs (a)(5)(i)(A) through (C) of this section. In determining the applicability of AMs specified for a sub-component of the NE multispecies fishery in paragraphs (a)(5)(i)(A) through (C) of this section, the Regional Administrator shall consider available information regarding the catch of regulated species and ocean pout by each sub-component of the NE multispecies fishery, plus each sub-component's share of any overage of the overall ACL for a particular stock caused by excessive catch by vessels outside of the FMP, exempted fisheries, or the Atlantic sea scallop fishery, as specified in this paragraph (a)(5), as appropriate.

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[FR Doc. 2015–09952 Filed 4–30–15; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

[Docket No. 140821699–5361–02]

RIN 0648–XD461

# Magnuson-Stevens Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; 2015 and 2016 Sector Operations Plans and 2015 Contracts and Allocation of Northeast Multispecies Annual Catch Entitlements

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

**ACTION:** Final rule.

**SUMMARY:** We have partially approved sector operations plans and contracts for fishing years 2015 and 2016, granting regulatory exemptions for fishing years 2015 and 2016, and providing Northeast multispecies annual catch entitlements to approved sectors for fishing year 2015. Approval of sector operations plans is necessary to allocate annual catch entitlements to the sectors and for the sectors to operate. The Northeast Multispecies Fishery Management Plan allows limited access permit holders to form sectors, and requires sectors to submit their operations plans and contracts to us, NMFS, for approval or disapproval. Approved sectors are exempt from certain effort control regulations and receive allocations of Northeast multispecies based on its members' fishing history.

**DATES:** Sector operations plans and regulatory exemptions are effective May 1, 2015, through April 30, 2017. Northeast multispecies annual catch entitlements for sectors are effective May 1, 2015, through April 30, 2016.

**ADDRESSES:** Copies of each sector's final operations plan and contract, and the environmental assessment (EA), are available from the NMFS Greater Atlantic Regional Fisheries Office: John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. These documents are also accessible via the Federal eRulemaking Portal: *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Liz Sullivan, Fishery Management Specialist, phone (978) 282–8493, fax (978) 281–9135. To review **Federal Register** documents referenced in this rule, you can visit: *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies.*

**SUPPLEMENTARY INFORMATION:**

## Background

Amendment 13 to the Northeast (NE) Multispecies Fishery Management Plan (FMP) (69 FR 22906, April 27, 2004) established a process for forming sectors within the NE multispecies (groundfish) fishery, and Amendment 16 to the FMP (74 FR 18262, April 9, 2010), followed by Framework Adjustment 45 to the FMP (76 FR 23042, April 25, 2011) and Framework 48 to the FMP (78 FR 26118; May 3, 2013), expanded and revised sector management.

The FMP defines a sector as ''[a] group of persons (three or more persons, none of whom have an ownership interest in the other two persons in the sector) holding limited access vessel permits who have voluntarily entered into a contract and agree to certain fishing restrictions for a specified period of time, and which has been granted a TAC(s) [*sic*] in order to achieve objectives consistent with applicable FMP goals and objectives.'' Sectors are self-selecting, meaning each sector can choose its members.

The NE multispecies sector management system allocates a portion of the NE multispecies stocks to each sector. These annual sector allocations are known as annual catch entitlements (ACE). These allocations are a portion of a stock's annual catch limit (ACL) available to commercial NE multispecies vessels within a sector, based on the collective fishing history of a sector's members. Currently, sectors may receive allocations of most large-mesh NE multispecies stocks with the exception of Atlantic halibut, windowpane flounder, Atlantic wolffish, and ocean pout, which are non-allocated. A sector determines how to harvest its ACEs and may decide to consolidate operations to fewer vessels.

Because sectors elect to receive an allocation under a quota-based system, the FMP grants sector vessels several ''universal'' exemptions from the FMP's effort controls. These universal exemptions apply to: Trip limits on allocated stocks; the Georges Bank (GB) Seasonal Closure Area; NE multispecies days-at-sea (DAS) restrictions; the requirement to use a 6.5-inch (16.5-cm) mesh codend when fishing with selective gear on GB; portions of the Gulf of Maine (GOM) Cod Protection Closures (as created by Framework 53; implemented concurrently with this rule); and the at-sea monitoring (ASM) coverage rate for sector vessels fishing on a monkfish DAS in the Southern New England (SNE) Broad Stock Area

(BSA) with extra-large mesh gillnets. The FMP prohibits sectors from requesting exemptions from permitting restrictions, gear restrictions designed to minimize habitat impacts, and reporting requirements.

Of the 24 approved sectors, we received operations plans and preliminary contracts for fishing years 2015 and 2016 from 17 sectors. The operations plans are similar to previously approved versions, but include operations spanning two fishing years, as well as additional exemption requests and proposals for industry-funded ASM plans. This is the first year that 2-year operations plans have been submitted by the sectors, as allowed in the Amendment 16 final rule. Two-year sector operations plans will help streamline the process for sector managers and reduce administrative burdens for both sectors and NMFS. Six sectors that have operated in past years did not submit operations plans or contracts. Four of these sectors now operate as state-operated permit banks as described below.

We have determined that the 17 sector operations plans and contracts that we have approved, and 19 of the 22 regulatory exemptions requested, in whole or partially, are consistent with the FMP's goals and objectives, and meet sector requirements outlined in the regulations at § 648.87. These 17 operations plans are similar to previously approved plans, but include a new exemption request. Copies of the operations plans and contracts, and the environmental assessment (EA), are available at *http://www.regulations.gov* and from NMFS (see **ADDRESSES**). One of the 17 sectors, Northeast Fishery Sector (NEFS) IV, proposes to operate as a private lease-only sector.

**Sector Allocations**

Based on sector enrollment as of February 25, 2015, we have projected fishing year 2015 allocations in this final rule. All permits enrolled in a sector, and the vessels associated with those permits, have until April 30, 2015, to withdraw from a sector and fish in the common pool for fishing year 2015. For fishing year 2016, we will set similar roster deadlines, notify permit holders of the fishing year 2016 deadlines, and allow permit holders to change sectors separate from the annual sector operations plans approval process. We will publish final sector ACEs and common pool sub-ACL totals, based upon final rosters, as soon as possible after the start of fishing year 2015, and again after the start of fishing year 2016.

We calculate the sector's allocation for each stock by summing its members' potential sector contributions (PSC) for a stock and then multiplying that total percentage by the available commercial sub-ACL for that stock, as approved in Framework 53 to the FMP. Table 1 shows the projected total PSC for each sector by stock for fishing year 2015. Tables 2 and 3 show the allocations that each sector will be allocated, in pounds and metric tons, respectively, for fishing year 2015, based on their preliminary fishing year 2015 rosters. At the start of the fishing year, we provide the final allocations, to the nearest pound, to the individual sectors, and we use those final allocations to monitor sector catch. While the common pool does not receive a specific allocation, the common pool sub-ACLs have been included in each of these tables for comparison.

We do not assign an individual permit separate PSCs for the Eastern GB cod or Eastern GB haddock; instead, we assign each permit a PSC for the GB cod stock and GB haddock stock. Each sector's GB cod and GB haddock allocations are then divided into an Eastern ACE and a Western ACE, based on each sector's percentage of the GB cod and GB haddock ACLs. For example, if a sector is allocated 4 percent of the GB cod ACL and 6 percent of the GB haddock ACL, the sector is allocated 4 percent of the commercial Eastern U.S./Canada Area GB cod total allowable catch (TAC) and 6 percent of the commercial Eastern U.S./Canada Area GB haddock TAC as its Eastern GB cod and haddock ACEs. These amounts are then subtracted from the sector's overall GB cod and haddock allocations to determine its Western GB cod and haddock ACEs. A sector may only harvest its Eastern GB cod ACEs in the Eastern U.S./Canada Area. However, Framework 51 implemented a mechanism that allows sectors to ''convert'' their Eastern GB haddock allocation into Western GB haddock allocation (79 FR 22421; April 22, 2014) and fish that converted ACE in Western GB.

At the start of fishing year 2015, we will withhold 20 percent of each sector's fishing year 2015 allocation until we finalize fishing year 2014 catch information. In the past, we have typically finalized the prior year's catch during the summer months. We expect to finalize 2014 catch information consistent with this past practice. We will allow sectors to transfer fishing year 2014 ACE for two weeks of the fishing year following our completion of year-end catch accounting to reduce or eliminate any fishing year 2014 overages. If necessary, we will reduce any sector's fishing year 2015 allocation to account for a remaining overage in fishing year 2014. We will follow the same process for fishing year 2016. Each year of the operations plans, we will notify the Council and sector managers of this deadline in writing and will announce this decision on our Web site at: *http://www.greateratlantic.fisheries.noaa.gov/.*

**Table 1. Cumulative PSC (percentage) each sector would receive by stock for fishing year 2015.***

| Sector Name | GB Cod† | GOM Cod | GB Haddock† | GOM Haddock | GB YT Flounder | SNE/MA YT Flounder‡ | CC/GOM YT Flounder‡ | American Plaice | Witch Flounder | GB Winter Flounder | GOM Winter Flounder | SNE/MA Winter Flounder‡ | Redfish | White Hake | Pollock |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| GB Cod Fixed Gear Sector (Fixed Gear Sector) | 27.67935808 | 2.508069188 | 5.76053223 | 1.842510985 | 0.012338526 | 0.335349757 | 2.900535294 | 0.978206727 | 2.132068565 | 0.027279132 | 12.88328537 | 1.803764995 | 2.737607611 | 5.696352686 | 7.378771941 |
| Maine Coast Community Sector (MCCS) | 0.209472107 | 4.593908731 | 0.038763949 | 2.557156843 | 0.003529542 | 0.659221791 | 1.050244077 | 7.550211604 | 5.059266898 | 0.006781752 | 1.964107993 | 0.192279966 | 2.49840078 | 4.391881855 | 3.788187256 |
| Maine Permit Bank | 0.133517853 | 1.150017115 | 0.044321553 | 1.121869513 | 0.013781801 | 0.031749784 | 0.317541132 | 1.163675492 | 0.726726396 | 0.000217063 | 0.425383217 | 0.017903914 | 0.820665465 | 1.651452916 | 1.687468044 |
| Northeast Coastal Communities Sector (NCCS) | 0.173979141 | 0.850761956 | 0.12156115 | 0.360314495 | 0.839234291 | 0.722094381 | 0.624502697 | 0.158814882 | 0.220556881 | 0.068242855 | 0.928696099 | 0.297060774 | 0.431476083 | 0.812934313 | 0.507473595 |
| NEFS 1 | 0 | 0.030624848 | 0 | 0.002485194 | 0 | 0 | 0.0375564 | 0.00855701 | 0.012746569 | 9.55103E-07 | 0.052060313 | 3.23398E-06 | 0 | 0 | 0 |
| NEFS 2 | 5.785693397 | 18.24336498 | 10.69102283 | 16.36546783 | 1.910229097 | 1.444212376 | 19.28095759 | 7.861111508 | 12.79803813 | 3.210723119 | 18.43848897 | 3.238568394 | 14.72518372 | 5.937102218 | 11.25997801 |
| NEFS 3 | 1.250350482 | 14.4542362 | 0.145886484 | 9.305432621 | 0.007146892 | 0.355112441 | 8.865102541 | 4.054725495 | 2.838467122 | 0.019617753 | 9.535130101 | 0.766907566 | 1.342069506 | 4.74811863 | 6.811962892 |
| NEFS 4 | 4.141388572 | 9.585261602 | 5.334211202 | 8.266201641 | 2.162259834 | 2.346367203 | 5.462860684 | 9.285854477 | 8.493233037 | 0.691705149 | 6.243231591 | 1.281664083 | 6.633415642 | 8.051799208 | 6.13956226 |
| NEFS 5 | 0.778804124 | 0.012758113 | 1.053822645 | 0.290496157 | 1.611585586 | 22.56725432 | 0.482700693 | 0.500854279 | 0.665881485 | 0.513664818 | 0.065815742 | 12.54858197 | 0.07677796 | 0.149356193 | 0.105160627 |
| NEFS 6 | 2.866433258 | 2.954570521 | 2.922333454 | 3.853800992 | 2.703502218 | 5.260657286 | 3.734992188 | 3.890740903 | 5.203709303 | 1.504147303 | 4.554949429 | 1.93996288 | 5.303308676 | 3.909202713 | 3.293398898 |
| NEFS 7 | 4.661795742 | 0.389982664 | 4.614051211 | 0.469838734 | 10.07880712 | 4.052928625 | 2.344003053 | 3.525287712 | 3.238628692 | 12.91879457 | 0.74671668 | 5.111936461 | 0.584977028 | 0.821143888 | 0.709754587 |
| NEFS 8 | 6.144290183 | 0.467653487 | 5.998225373 | 0.209189789 | 11.25214114 | 5.962375546 | 6.429443155 | 1.720618673 | 2.570311936 | 15.50532661 | 3.163884539 | 10.02749381 | 0.548979457 | 0.512752812 | 0.607472949 |
| NEFS 9 | 14.22968847 | 1.745530387 | 11.59904763 | 4.803066812 | 26.77690025 | 7.896063683 | 10.42613668 | 8.267330649 | 8.274748241 | 39.53996927 | 2.450067748 | 18.36278683 | 5.824426848 | 4.150679805 | 4.226744874 |
| NEFS 10 | 0.729079458 | 5.211425491 | 0.25110816 | 2.537642334 | 0.001554983 | 0.547575942 | 12.6910265 | 1.70226779 | 2.393309197 | 0.010736748 | 17.86097648 | 0.727751379 | 0.545032258 | 0.893630738 | 1.388211048 |
| NEFS 11 | 0.406460279 | 13.61584944 | 0.038112035 | 3.214095399 | 0.001526991 | 0.019512587 | 2.580229504 | 2.095916251 | 2.072650077 | 0.003308214 | 2.248924914 | 0.021603495 | 1.982725124 | 4.830691483 | 9.436352239 |
| NEFS 13 | 7.962064191 | 0.897737741 | 15.96691698 | 0.952525702 | 24.74483888 | 18.82290704 | 4.990558725 | 5.158650568 | 6.203321063 | 7.237218376 | 2.333512423 | 10.97508139 | 3.977258859 | 1.744848444 | 2.270555669 |
| New Hampshire Permit Bank | 0.001520057 | 1.139033486 | 0.000259488 | 0.031174312 | 2.03069E-05 | 1.9297E-05 | 0.021779341 | 0.028468044 | 0.006158356 | 3.23661E-06 | 0.060320275 | 7.80481E-05 | 0.019373158 | 0.081220063 | 0.110853509 |
| Sustainable Harvest Sector 1 | 20.64126839 | 19.67078936 | 34.32389115 | 42.76093197 | 14.08003285 | 8.306256132 | 13.24545693 | 39.48139985 | 34.43846704 | 17.40442314 | 10.27273026 | 19.28481204 | 51.2369025 | 50.73902733 | 39.56037962 |
| Sustainable Harvest Sector 3 | 0.276889401 | 0.148129006 | 0.381148841 | 0.065262008 | 2.176947963 | 2.389710695 | 1.109489783 | 0.617194407 | 0.616807632 | 0.567337392 | 1.316858882 | 1.350127027 | 0.170949982 | 0.147986599 | 0.04944612 |
| **Sectors Total** | **98.07205319** | **97.66970431** | **99.28521636** | **99.00946333** | **98.37637828** | **81.71936888** | **96.59511696** | **98.04988632** | **97.96509661** | **99.22949745** | **95.54514102** | **87.94836826** | **99.45953066** | **99.27018187** | **99.33173414** |
| Common Pool | 1.92794681 | 2.330295692 | 0.714783636 | 0.990536672 | 1.623621723 | 18.28063112 | 3.404883037 | 1.950113682 | 2.034903388 | 0.770502551 | 4.454858982 | 12.05163174 | 0.540469341 | 0.729818134 | 0.668265864 |

* The data in this table are based on preliminary fishing year 2015 sector rosters.

† For fishing year 2015, 6.94 percent of the GB cod ACL would be allocated for the Eastern U.S./Canada Area, while 81.62 percent of the GB haddock ACL would be allocated for the Eastern U.S./Canada Area.

‡ SNE/MA Yellowtail Flounder refers to the SNE/Mid-Atlantic stock. CC/GOM Yellowtail Flounder refers to the Cape Cod/GOM stock.

**Table 2. ACE (in 1,000 lbs), by stock, for each sector for fishing year 2015.*#^**

| Sector Name | GB Cod East | GB Cod West | GOM Cod | GB Haddock East | GB Haddock West | GOM Haddock | GB YT Flounder | SNE/MA YT Flounder | CC/GOM YT Flounder | American Plaice | Witch Flounder | GB Winter Flounder | GOM Winter Flounder | SNE/MA Winter Flounder | Redfish Estimated | White Hake | Pollock |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fixed Gear Sector | 76 | 1015 | 11 | 2255 | 508 | 39 | 0 | 4 | 29 | 30 | 29 | 1 | 111 | 52 | 666 | 545 | 2232 |
| MCCS | 1 | 8 | 21 | 15 | 3 | 54 | 0 | 8 | 11 | 234 | 68 | 0 | 17 | 6 | 608 | 421 | 1146 |
| Maine Permit Bank | 0 | 5 | 5 | 17 | 4 | 24 | 0 | 0 | 3 | 36 | 10 | 0 | 4 | 1 | 200 | 158 | 510 |
| NCCS | 0 | 6 | 4 | 48 | 11 | 8 | 4 | 9 | 6 | 5 | 3 | 3 | 8 | 9 | 105 | 78 | 153 |
| NEFS 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NEFS 2 | 16 | 212 | 83 | 4186 | 943 | 346 | 8 | 18 | 195 | 244 | 172 | 134 | 159 | 93 | 3582 | 568 | 3406 |
| NEFS 3 | 3 | 46 | 66 | 57 | 13 | 197 | 0 | 4 | 90 | 126 | 38 | 1 | 82 | 22 | 326 | 455 | 2060 |
| NEFS 4 | 11 | 152 | 44 | 2089 | 470 | 175 | 9 | 29 | 55 | 288 | 114 | 29 | 54 | 37 | 1614 | 771 | 1857 |
| NEFS 5 | 2 | 29 | 0 | 413 | 93 | 6 | 7 | 277 | 5 | 16 | 9 | 21 | 1 | 361 | 19 | 14 | 32 |
| NEFS 6 | 8 | 105 | 13 | 1144 | 258 | 81 | 12 | 65 | 38 | 121 | 70 | 63 | 39 | 56 | 1290 | 374 | 996 |
| NEFS 7 | 13 | 171 | 2 | 1807 | 407 | 10 | 43 | 50 | 24 | 109 | 44 | 539 | 6 | 147 | 142 | 79 | 215 |
| NEFS 8 | 17 | 225 | 2 | 2349 | 529 | 4 | 48 | 73 | 65 | 53 | 35 | 646 | 27 | 289 | 134 | 49 | 184 |
| NEFS 9 | 39 | 522 | 8 | 4542 | 1023 | 101 | 115 | 97 | 105 | 257 | 111 | 1648 | 21 | 529 | 1417 | 397 | 1278 |
| NEFS 10 | 2 | 27 | 24 | 98 | 22 | 54 | 0 | 7 | 128 | 53 | 32 | 0 | 154 | 21 | 133 | 86 | 420 |
| NEFS 11 | 1 | 15 | 62 | 15 | 3 | 68 | 0 | 0 | 26 | 65 | 28 | 0 | 19 | 1 | 482 | 463 | 2854 |
| NEFS 13 | 22 | 292 | 4 | 6252 | 1408 | 20 | 106 | 231 | 50 | 160 | 83 | 302 | 20 | 316 | 968 | 167 | 687 |
| New Hampshire Permit Bank | 0 | 0 | 5 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 5 | 8 | 34 |
| Sustainable Harvest Sector 1 | 56 | 757 | 90 | 13439 | 3026 | 903 | 61 | 102 | 134 | 1226 | 463 | 726 | 89 | 555 | 12464 | 4858 | 11966 |
| Sustainable Harvest Sector 3 | 1 | 10 | 1 | 149 | 34 | 1 | 9 | 29 | 11 | 19 | 8 | 24 | 11 | 39 | 42 | 14 | 15 |
| **Sectors Total** | **268** | **3596** | **446** | **38874** | **8753** | **2091** | **423** | **1003** | **975** | **3044** | **1317** | **4137** | **826** | **2532** | **24194** | **9505** | **30045** |
| Common Pool | 5 | 71 | 11 | 280 | 63 | 21 | 7 | 224 | 34 | 61 | 27 | 32 | 38 | 347 | 131 | 70 | 202 |

*The data in this table are based on preliminary fishing year 2015 sector rosters.

#Numbers are rounded to the nearest thousand lbs. In some cases, this table shows an allocation of 0, but that sector may be allocated a small amount of that stock in tens or hundreds pounds.

^ The data in the table represent the total allocations to each sector. NMFS will withhold 20 percent of a sector's total ACE at the start of the fishing year to finalize catch accounting from the previous fishing year.

**Table 3. ACE (in metric tons), by stock, for each sector for fishing year 2015.*#^**

| Sector Name | GB Cod East | GB Cod West | GOM Cod | GB Haddock East | GB Haddock West | GOM Haddock | GB YT Flounder | SNE/MA YT Flounder | CC/GOM YT Flounder | American Plaice | Witch Flounder | GB Winter Flounder | GOM Winter Flounder | SNE/MA Winter Flounder | Redfish Estimated | White Hake | Pollock |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fixed Gear Sector | 34 | 460 | 5 | 1023 | 230 | 18 | 0 | 2 | 13 | 14 | 13 | 1 | 51 | 24 | 302 | 247 | 1012 |
| MCCS | 0 | 3 | 10 | 7 | 2 | 24 | 0 | 4 | 5 | 106 | 31 | 0 | 8 | 3 | 276 | 191 | 520 |
| Maine Permit Bank | 0 | 2 | 2 | 8 | 2 | 11 | 0 | 0 | 1 | 16 | 4 | 0 | 2 | 0 | 91 | 72 | 232 |
| NCCS | 0 | 3 | 2 | 22 | 5 | 3 | 2 | 4 | 3 | 2 | 1 | 1 | 4 | 4 | 48 | 35 | 70 |
| NEFS 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| NEFS 2 | 7 | 96 | 38 | 1899 | 428 | 157 | 4 | 8 | 88 | 111 | 78 | 61 | 72 | 42 | 1625 | 258 | 1545 |
| NEFS 3 | 2 | 21 | 30 | 26 | 6 | 89 | 0 | 2 | 41 | 57 | 17 | 0 | 37 | 10 | 148 | 206 | 935 |
| NEFS 4 | 5 | 69 | 20 | 947 | 213 | 79 | 4 | 13 | 25 | 131 | 52 | 13 | 24 | 17 | 732 | 350 | 842 |
| NEFS 5 | 1 | 13 | 0 | 187 | 42 | 3 | 3 | 126 | 2 | 7 | 4 | 10 | 0 | 164 | 8 | 6 | 14 |
| NEFS 6 | 4 | 48 | 6 | 519 | 117 | 37 | 5 | 29 | 17 | 55 | 32 | 28 | 18 | 25 | 585 | 170 | 452 |
| NEFS 7 | 6 | 78 | 1 | 819 | 185 | 5 | 20 | 23 | 11 | 50 | 20 | 244 | 3 | 67 | 65 | 36 | 97 |
| NEFS 8 | 8 | 102 | 1 | 1065 | 240 | 2 | 22 | 33 | 29 | 24 | 16 | 293 | 12 | 131 | 61 | 22 | 83 |
| NEFS 9 | 18 | 237 | 4 | 2060 | 464 | 46 | 52 | 44 | 48 | 116 | 50 | 748 | 10 | 240 | 643 | 180 | 580 |
| NEFS 10 | 1 | 12 | 11 | 45 | 10 | 24 | 0 | 3 | 58 | 24 | 15 | 0 | 70 | 10 | 60 | 39 | 190 |
| NEFS 11 | 1 | 7 | 28 | 7 | 2 | 31 | 0 | 0 | 12 | 30 | 13 | 0 | 9 | 0 | 219 | 210 | 1295 |
| NEFS 13 | 10 | 132 | 2 | 2836 | 639 | 9 | 48 | 105 | 23 | 73 | 38 | 137 | 9 | 143 | 439 | 76 | 312 |
| New Hampshire Permit Bank | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 4 | 15 |
| Sustainable Harvest Sector 1 | 26 | 343 | 41 | 6096 | 1373 | 410 | 27 | 46 | 61 | 556 | 210 | 329 | 40 | 252 | 5653 | 2204 | 5428 |
| Sustainable Harvest Sector 3 | 0 | 5 | 0 | 68 | 15 | 1 | 4 | 13 | 5 | 9 | 4 | 11 | 5 | 18 | 19 | 6 | 7 |
| **Sectors Total** | **122** | **1631** | **202** | **1763 3** | **3970** | **949** | **192** | **455** | **442** | **1381** | **598** | **1876** | **375** | **1149** | **10974** | **4311** | **13628** |
| Common Pool | 2 | 32 | 5 | 127 | 29 | 9 | 3 | 102 | 16 | 27 | 12 | 15 | 17 | 157 | 60 | 32 | 92 |

*The data in this table are based on preliminary fishing year 2015 sector rosters.

#Numbers are rounded to the nearest metric ton, but allocations are made in pounds. In some cases, this table shows a sector allocation of 0 metric tons, but that sector may be allocated a small amount of that stock in pounds.

^ The data in the table represent the total allocations to each sector. NMFS will withhold 20 percent of a sector's total ACE at the start of the fishing year to finalize catch accounting from the previous fishing year.

**Sector Operations Plans and Contracts**

As previously stated, we received 17 sector operations plans and contracts by the September 2, 2014, deadline for fishing years 2015 and 2016. Each sector elected to submit a single document that is both its contract and operations plan. Therefore, these submitted operations plans not only contain the rules under which each sector would fish, but also provide the legal contract that binds each member to the sector. All sectors' proposed operations plans are for two fishing years—2015 and 2016. Each sector's operations plan, and each sector's members, must comply with the regulations governing sectors, found at § 648.87. In addition, each sector must conduct fishing activities as detailed in its approved operations plan.

Participating vessels are required to comply with all pertinent Federal fishing regulations, except as specifically exempted in the letter of authorization (LOA) issued by the Regional Administrator, which details any approved exemptions from the regulations. If, during a fishing year, or between fishing years 2015 and 2016, a sector requests an exemption that we have already granted, or proposes a change to administrative provisions, we may amend the sector operations plans. Should any amendments require modifications to LOAs, we would include these changes in updated LOAs and provide these to the appropriate sector members.

As in previous years, we retain the right to revoke exemptions in-season for the following reasons: If we determine that the exemption jeopardizes management measures, objectives, or rebuilding efforts; if the exemption results in unforeseen negative impacts on other managed fish stocks, habitat, or protected resources; if the exemption causes enforcement concerns; if catch from trips utilizing the exemption cannot adequately be monitored; or if a sector is not meeting certain administrative or operational requirements. If it becomes necessary to revoke an exemption, we will do so through a process consistent with the Administrative Procedure Act.

Each sector is required to ensure that it does not exceed its ACE during the fishing year. Sector vessels are required to retain all legal-sized allocated NE multispecies stocks, unless a sector is granted an exemption allowing its member vessels to discard legal-sized unmarketable fish at sea. Catch (defined as landings and discards) of all allocated NE multispecies stocks by a sector's vessels count against the sector's allocation. Catch from a sector trip (*e.g.,* not fishing in a NE multispecies exempted fishery or with exempted gear) targeting dogfish, monkfish, skate, and lobster (with non-trap gear) would be deducted from the sector's ACE because these trips use gear capable of catching groundfish. This includes trips that have declared into the small mesh exemption (described below), because vessels fishing under this sector exemption, *i.e.,* vessels fishing with both small mesh and large mesh during the same trip, are considered a sector trip for purposes of monitoring ACE. Catch from a trip in an exempted fishery does not count against a sector's allocation because the catch is assigned to a separate ACL sub-component.

For fishing years 2010 and 2011, there was no requirement for an industry-funded ASM program, and we were able to fund an ASM program with a target ASM coverage rate of 30 percent of all trips. In addition, we provided 8-percent observer coverage through the Northeast Fishery Observer Program (NEFOP), which helps to support the Standardized Bycatch Reporting Methodology (SBRM) and stock assessments. This resulted in an overall target coverage rate of 38 percent, between ASM and NEFOP, for fishing years 2010 and 2011. Beginning in fishing year 2012, we have conducted an annual analysis to determine the total coverage that would be necessary to achieve the same level of precision as attained by the 38-percent total coverage target used for fishing years 2010 and 2011. Since fishing year 2012, industry has been required to pay for their costs of ASM coverage, while we continued to fund NEFOP. However, we were able to fund the industry's portion of ASM costs and NEFOP coverage in fishing years 2012 through 2014. Table 4 shows the annual target coverage rates.

TABLE 4—HISTORIC TARGET COVERAGE RATE FOR MONITORING

| Fishing year | Total target coverage rate (percent) | ASM target coverage rate (percent) | NEFOP target coverage rate (percent) | Funding source |
|---|---|---|---|---|
| 2010 | 38 | 30 | 8 | NMFS |
| 2011 | 38 | 30 | 8 | NMFS |
| 2012 | 25 | 17 | 8 | NMFS |
| 2013 | 22 | 14 | 8 | NMFS |
| 2014 | 26 | 18 | 8 | NMFS |

Due to funding changes that are required by the NE Omnibus SBRM Amendment, we expect that sector vessels will be responsible for paying the at-sea portion of costs associated with the sector ASM program before the end of the 2015 fishing year. Thus, sectors will be responsible for designing, implementing, and funding an ASM program in fishing years 2015 and 2016 that will provide a level of ASM coverage specified by NMFS. Amendment 16 regulations require NMFS to specify a level of ASM coverage that is sufficient to meet the same coefficient of variation (CV) specified in the SBRM and accurately monitor sector operations. Framework 48 clarified the level of ASM coverage necessary to meet these goals. Framework 48 determined that the CV level should be achieved at the overall stock level, which is consistent with the level NMFS determined was necessary in fishing year 2013. Framework 48 also amended the goals of the sector monitoring program to include achieving an accuracy level sufficient to minimize effects of potential monitoring bias.

Taking the provisions of Framework 48 into account, and interpreting the ASM monitoring provision in the context of Magnuson-Stevens Act requirements and National Standards, we have determined that the appropriate level of ASM coverage should be set at the level that meets the CV requirement specified in the SBRM and minimizes the cost burden to sectors and NMFS to the extent practicable, while still providing a reliable estimate of overall catch by sectors needed for monitoring ACEs and ACLs. Based on this standard, NMFS has determined that the total appropriate target coverage rate for fishing year 2015 is 24 percent. We

expect ASM coverage to be 20 percent and NEFOP coverage to be 4 percent (based on the Omnibus SBRM, as proposed), covering a total of 24 percent of all sector trips, with the exception of trips using a few specific exemptions, as described later in this rule. We will use discards derived from these observed and monitored trips to calculate discards for unobserved sector trips. We have published a more detailed summary of the supporting information, explanation and justification for this decision at: *http://www.greateratlantic.fisheries.noaa.gov/ro/fso/reports/Sectors/ASM/FY2015_Multispecies_Sector_ASM_Requirements_Summary.pdf.*

The draft operations plans submitted in September 2014 included industry-funded ASM plans to be used for fishing year 2015. We gave sectors the option to design their own programs in compliance with regulations, or elect to adopt the program that we have used in previous fishing years. Four sectors chose to adopt the program we used in previous years. We approved the sector-proposed program for the remaining 12 sectors. ASM programs proposed by the sectors are described in detail later in this final rule.

We are currently looking at how industry funding of its costs for the ASM program will affect our data collection systems, especially the pre-trip notification system (PTNS), and have begun working on an implementation plan to help ensure a seamless transition when the industry assumes responsibility for at-sea costs in 2015. To ensure that the ASM programs continue to provide sufficient coverage, the Regional Administrator is authorized to adjust operational standards such as vessel selection protocols as needed, consistent with the Administrative Procedure Act. We will continue to keep the sector managers informed about any changes or updates to coverage data collection and notification requirements.

Our ability to fund our portion of costs for ASM coverage above SBRM coverage levels for the entire 2015 and 2016 fishing years is still not known at this time due to budget uncertainties. Currently, funding for our portion of ASM costs is expected to expire before the end of the 2015 fishing year. If we have insufficient funding available for our portion of coverage costs beyond that time, we may need to consider other measures, including emergency action, to allow sectors to continue fishing while still ensuring that we can adequately monitor sector catch for management purposes.

Each sector contract details the method for initial ACE sub-allocation to sector members. For fishing years 2015 and 2016, each sector has proposed that each sector member could harvest an amount of fish equal to the amount each individual member's permit contributed to the sector, as modified by the sector for reserves or other management choices. Each sector operations plan submitted for fishing years 2015 and 2016 states that the sector would withhold an initial reserve from the sector's ACE sub-allocation to each individual member to prevent the sector from exceeding its ACE. A sector and sector members can be held jointly and severally liable for ACE overages, discarding legal-sized fish, and/or misreporting catch (landings or discards). Each sector contract provides procedures to enforce the sector operations plan, explains sector monitoring and reporting requirements, presents a schedule of penalties for sector plan violations, and provides sector managers with the authority to issue stop fishing orders to sector members who violate provisions of the operations plan and contract.

Sectors are required to monitor their allocations and catch. To help ensure a sector does not exceed its ACE, each sector operations plan explains sector monitoring and reporting requirements, including a requirement to submit weekly catch reports to us. If a sector reaches an ACE threshold (specified in the operations plan), the sector must provide us with sector allocation usage reports on a daily basis. Once a sector's allocation for a particular stock is caught, that sector is required to cease all sector fishing operations in that stock area until it acquires more ACE, unless that sector has an approved plan to fish without ACE for that stock. ACE may be transferred between sectors, but transfers to or from common pool vessels is prohibited. Within 60 days of when we complete year-end catch accounting, each sector is required to submit an annual report detailing the sector's catch (landings and discards), enforcement actions, and pertinent information necessary to evaluate the biological, economic, and social impacts of each sector.

**Granted Exemptions for Fishing Years 2015 and 2016**

*Previously Granted Exemptions Granted for Fishing Years 2015 and 2016 (1–16)*

We granted exemptions from the following requirements for fishing years 2015 and 2016, all of which have been previously requested and granted: (1) 120-day block out of the fishery required for Day gillnet vessels; (2) 20-day spawning block out of the fishery required for all vessels; (3) prohibition on a vessel hauling another vessel's gillnet gear; (4) limits on the number of gillnets that may be hauled on GB when fishing under a NE multispecies/monkfish DAS; (5) limits on the number of hooks that may be fished; (6) DAS Leasing Program length and horsepower restrictions; (7) prohibition on discarding; (8) daily catch reporting by sector managers for sector vessels participating in the Closed Area (CA) I Hook Gear Haddock Special Access Program (SAP); (9) prohibition on fishing inside and outside of the CA I Hook Gear Haddock SAP while on the same trip; (10) prohibition on a vessel hauling another vessel's hook gear; (11) the requirement to declare an intent to fish in the Eastern U.S./Canada SAP and the CA II Yellowtail Flounder/Haddock SAP prior to leaving the dock; (12) gear requirements in the Eastern U.S./Canada Management Area; (13) seasonal restrictions for the Eastern U.S./Canada Haddock SAP; (14) seasonal restrictions for the CA II Yellowtail Flounder/Haddock SAP; (15) sampling exemption; and (16) prohibition on groundfish trips in the Nantucket Lightship Closed Area. A detailed description of the previously granted exemptions and supporting rationale can be found in the applicable final rules identified in Table 5 below.

TABLE 5—EXEMPTIONS FROM PREVIOUS FISHING YEARS THAT ARE GRANTED IN FISHING YEARS 2015 AND 2016

| Exemptions | Rulemaking | Date of initial approval | Citation |
|---|---|---|---|
| 1–8, 12 | Fishing Year 2011 Sector Operations Final Rule | April 25, 2011 | 76 FR 23076. |
| 9–11 | Fishing Year 2012 Sector Operations Final Rule | May 2, 2012 | 77 FR 26129. |
| 13–15 | Fishing Year 2013 Sector Operations Interim Final Rule | May 2, 2013 | 78 FR 25591. |
| 16 | Fishing Year 2014 Sector Operations Final Rule | April 28, 2014 | 79 FR 23278. |

NE Multispecies **Federal Register** documents can be found at *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies/.*

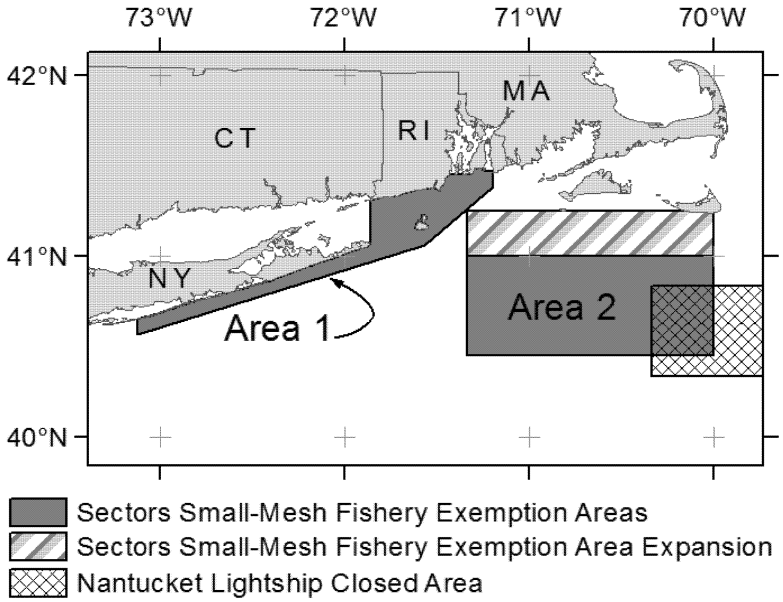
*Exemptions of Concern That Are Granted for Fishing Years 2015 and 2016 (17–19)*

(17) Prohibition on Combining Small-Mesh Exempted Fishery and Sector Trips

For fishing year 2014, sectors requested and we granted an exemption that would allow vessels to possess and use small-mesh and large-mesh trawl gear on a single trip, within portions of the SNE regulated mesh areas (RMA). Sectors proposed allowing vessels using this exemption to fish with smaller mesh in two discrete areas that have been shown to have minimal amounts of regulated species and ocean pout. See the 2014 Sector Operations Plans Final Rule (79 FR 23278; April 28, 2014) for a complete description of the previously granted exemption.

For fishing years 2015 and 2016, sectors requested a similar exemption, but with a revised northern border of the eastern Small-Mesh Exemption Area 2, shifted 15 minutes north. This expansion will allow for greater opportunities for sector vessels to target small-mesh species. The coordinates and maps for these two areas are show in Figure 1.

**Figure 1 – Sectors Small-Mesh Exemption Areas 1 and 2, as modified**




Sector Small-Mesh Fishery Exemption Area 1 is bounded by the following coordinates connected in the order listed by straight lines, except where otherwise noted:

| Point | N. Latitude | W. Longitude | Note |
|---|---|---|---|
| A ..... | 40°39.2′ | 73°07.0′ | ..... |
| B ..... | 40°34.0′ | 73°07.0′ | ..... |
| C ..... | 41°03.5′ | 71°34.0′ | ..... |
| D ..... | 41°23.0′ | 71°11.5′ | ..... |
| E ..... | 41°27.6′ | 71°11.5′ | (1) |
| F ..... | 41°18.3′ | 71°51.5′ | ..... |
| G ..... | 41°04.3′ | 71°51.5′ | (2) |
| A ..... | 40°39.2′ | 73°07.0′ | ..... |

(1) From POINT E to POINT F along the southernmost coastline of Rhode Island and crossing all bays and inlets following the COLREGS Demarcation Lines defined in 33 CFR part 80.

(2) From POINT G back to POINT A along the southernmost coastline of Long Island, NY, and crossing all bays and inlets following the COLREGS Demarcation Lines defined in 33 CFR part 80.

For fishing years 2015 and 2016, Sector Small-Mesh Fishery Exemption Area 2 is bound by the following coordinates connected in the order listed by straight lines. Sector vessels cannot fish the small-mesh portion of their trip using this exemption in the Nantucket Lightship Closed Area where the two areas overlap.

| Point | N. Latitude | W. Longitude |
|---|---|---|
| H ..... | 41°15.0′ N. | 71°20.0′ W. |
| I ..... | 41°15.0′ N. | 70°00.0′ W. |
| J ..... | 40°27.0′ N. | 70°00.0′ W. |
| K ..... | 40°27.0′ N. | 71°20.0′ W. |
| H ..... | 41°15.0′ N. | 71°20.0′ W. |

As was granted in fishing year 2014, one of three trawl gear modifications is required when using small mesh: Drop-chain sweep with a minimum of 12 inches (30.48 cm) in length; a large-mesh belly panel with a minimum of 32-inch (81.28-cm) mesh size; or an excluder grate secured forward of the codend with an outlet hole forward of the grate with bar spacing of no more than 1.97 inches (5.00 cm) wide. These gear modifications, when fished properly, have been shown to reduce the catch of legal and sub-legal groundfish stocks. Requiring these modifications is intended to also reduce the incentive for a sector vessel to target groundfish with small mesh.

A vessel using this exemption is required to meet the same NEFOP and ASM coverage as standard groundfish trips (*i.e.*, a total of 24 percent in fishing year 2015). To facilitate proper coverage levels and assist with enforcement, the vessel is required to declare their intent to use small mesh to target non-regulated species by submitting a trip start hail through its vessel monitoring system (VMS) unit prior to departure. Trips declaring this exemption must stow their small-mesh gear and use their large-mesh gear first, and once finished with the large mesh, must submit a Multispecies Catch Report via VMS of all catch on board at that time. Once the Catch Report is sent, the vessel can then deploy small mesh with the required modifications in the specific areas (see map above), outside of the Nantucket Lightship Closed Area, at which point, the large mesh cannot be redeployed. Any legal-sized allocated groundfish stocks caught during these small-mesh

hauls must be landed and the associated landed weight (dealer or vessel trip report (VTR)) will be deducted from the sector's ACE.

We received two comments in support of granting this exemption as proposed, including the modification to the Sector Small-Mesh Fishery Exemption Area 2 (see map). One commenter indicated that the provisions (*e.g.* trip start hails, gear stowage requirements, catch report submission, and gear modifications) allow for a higher level of enforceability.

As in fishing year 2014, we are concerned about vessels potentially catching groundfish, including bycatch of juvenile fish, in the requested exemption area with small-mesh nets. The expansion of the Small-Mesh Exemption Area 2 by 15 minutes north could increase this potential, because more groundfish are found in the expansion area. The three gear modifications proposed for this exemption could mitigate catch of regulated species when properly installed, but none have been shown to completely eliminate the catch of regulated species.

Based on the comments received, we have granted this exemption as proposed for fishing years 2015 and 2016. We will be reviewing data from 2014 and plan to closely monitor the catch from these exempted trips. If it is determined that this exemption is having a negative impact on groundfish stocks, we would consider revoking this exemption during the fishing year.

(18) Limits on the Number of Gillnets on Day Gillnet Vessels

The FMP limits the number of gillnets a Day gillnet vessel may fish in the groundfish RMAs to prevent an uncontrolled increase in the number of nets being fished, thus undermining applicable DAS effort controls. The limits are specific to the type of gillnet within each RMA: 100 gillnets (of which no more than 50 can be roundfish gillnets) in the GOM RMA (§ 648.80(a)(3)(iv)); 50 gillnets in the GB RMA (§ 648.80(a)(4)(iv)); and 75 gillnets in the Mid-Atlantic (MA) RMA (§ 648.80(b)(2)(iv)). We previously granted this exemption in fishing years 2010, 2011, and 2012 to allow sector vessels to fish up to 150 nets (any combination of flatfish or roundfish nets) in any RMA to provide greater operational flexibility to sector vessels in deploying gillnet gear. Sectors argued that the gillnet limits were designed to control fishing effort and are no longer necessary because a sector's ACE limits overall fishing mortality.

Previous effort analysis of all sector vessels using gillnet gear indicated an increase in gear used in the RMA which could lead to an increase in interactions with protected species. While a sector's ACE is designed to limit a stock's fishing mortality, fishing effort may affect other species. This increased effort could ultimately lead to a rise in interactions with protected species; however, we have not identified trends indicating this. Additionally, a take reduction plan has been implemented to reduce bycatch in the fisheries affecting these species, and there is continual monitoring of protected species bycatch.

For fishing year 2013, based on the comments received and the concern for spawning GOM cod, we restricted the use of this exemption to better protect spawning cod. Therefore, a vessel fishing in the GOM RMA was able to use this exemption seasonally, but was restricted to the 100-net gillnet limit in blocks 124 and 125 in May, and in blocks 132 and 133 in June. A vessel fishing in the GB RMA, SNE RMA, MA RMA, and the GOM outside of these times and areas did not have this additional restriction. We granted this exemption with the same GOM seasonal restrictions for fishing year 2014.

The November 2014 interim action implemented to protect GOM cod (79 FR 67362; November 13, 2014) revoked this exemption for all of the GOM for the remainder of fishing year 2014, given concerns relating to mortality of GOM cod caused by continuous fishing by gillnets left in the water and the potential to disrupt spawning when cod are caught.

For fishing years 2015 and 2016, we proposed to grant the exemption for fishing years 2015 and 2016 when fishing in all RMAs except the GOM, and to deny the exemption for the GOM. Therefore, vessels fishing in the GOM under the Day boat gillnet category would be restricted to no more than 100 nets, only 50 of which may be roundfish nets.

We received three comments on to this exemption. Oceana was supportive of the proposal to deny the exemption in the GOM RMA, but urged us to also deny the exemption in other RMAs, to protect GB cod. Conversely, two sector-related groups disagreed with our proposal to deny the exemption for the GOM, but supported the proposal to grant it in the other RMAs. They referenced the fishing mortality limits already placed on sectors by ACLs and the sector's resulting allocations, and stated that with such a low GOM cod ACL, Day gillnet vessels will already be strategizing to avoid catching cod, and therefore don't need further limits on the amount of gear they can use.

While the low ACLs for GOM cod will help reduce the fishing pressure on GOM cod, we feel it is important to maintain the FMP's limit on the amount of gillnet gear in the GOM that may catch GOM cod, in part because of the low sub-ACL set for GOM cod. Also, we are particularly concerned with the potential interactions with spawning GOM cod and the potential for long-term detrimental effects if spawning aggregations are disrupted. Sectors have the flexibility to declare into the Trip boat gillnet category, which have no limits on the number of nets allowed in the GOM but are not allowed to leave gear unattended. At the current time, we do not think it is necessary to deny this exemption outside of the GOM RMA. For a full description of the comments and further discussion of these issues, please see the Comments and Responses Section below.

Based on the comments received and the concern for spawning cod, we are partially granting and denying this sector exemption request for fishing years 2015 and 2016, as we proposed in the proposed rule. Day gillnet vessels will be restricted to a 150-gillnet limit in the GB, SNE, and MA RMAs; in GOM RMA, the vessel will be restricted to a 100-gillnet limit (of which no more than 50 can be roundfish gillnets).

(19) Regulated Mesh Size 6.5 Inch (16.5 cm) or Greater, for Directed Redfish Trips

Minimum mesh size restrictions (§ 648.80(a)(3)(i), (a)(4)(i), (b)(2)(i), and (c)(2)(i)) were implemented under previous groundfish actions to reduce overall mortality on groundfish stocks, change the selection pattern of the fishery to target larger fish, improve survival of sublegal fish, and allow sublegal fish more opportunity to spawn before entering the fishery. Beginning in fishing year 2012, we have granted exemptions that allow sector vessels to target redfish, the smallest species of regulated groundfish, with a sub-legal size mesh codend, ranging from 4.5 inches (11.4 cm) to 6 inches (15.2 cm) (see Table 6). In order to use these previous exemptions, sectors have been required to meet an 80-percent threshold of redfish catch, relative to groundfish catch, and a 5-percent discard threshold of total groundfish, including redfish. These thresholds were intended to ensure that a vessel using the exemption effectively targets redfish and does not target other species with a smaller mesh, and attempts to avoid catching sub-legal groundfish. The thresholds were based on

Component 2 of the REDNET report (Kanwit et al. 2013), which used a 4.5-inch mesh codend, and observer data for trips conducted in fishing year 2012. REDNET is a group that includes the Maine Department of Marine Resources, the Massachusetts Division of Marine Fisheries, and the University of Massachusetts School for Marine Science and Technology, who joined with other members of the scientific community and the industry to develop a research plan to develop a sustainable, directed, redfish trawl fishery in the GOM. Each year, we have changed the exemption at the sectors' request in an attempt to balance the goal of increasing use of the exemption, and therefore facilitate access to this healthy stock, while preventing misuse and ensuring it is consistent with the FMP's goals and objectives.

TABLE 6—REDFISH EXEMPTIONS BY FISHING YEAR

| Exemptions | Rulemaking | Date | Citation |
|---|---|---|---|
| 6.0 inch (15.2 cm) with 100% NMFS-funded coverage. | FY 2012 Sector Operations Final Rule ... | May 2, 2012 ..... | 77 FR 26129. |
| 4.5 inch (11.4 cm) with 100% NMFS-funded coverage. | FY 2012 Redfish Exemption Final Rule .. | March 5, 2013 ..... | 78 FR 14226. |
| 4.5 inch (11.4 cm) with 100% Industry-funded coverage. | FY 2013 Sector Operations Interim Final Rule. | May 2, 2013 ..... | 78 FR 25591. |
| 6.0 inch (15.2 cm) with standard observer coverage. | FY 2014 Sector Operations Final Rule ... | April 28, 2014 ..... | 79 FR 23278. |

NE Multispecies **Federal Register** documents can be found at *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies.*

For fishing years 2012 and 2013, the exemption required 100-percent monitoring with either an ASM or observer on every trip, primarily because of concerns over a greater retention of sub-legal groundfish, as well as non-allocated species and bycatch. In fishing year 2012, we found that allowing trips that are randomly selected for federally funded NEFOP or ASM coverage provided an incentive to take an exemption trip when selected for coverage, thereby reducing the number of observers/monitors available to cover standard sector trips (*i.e.,* trips not utilizing this exemption). If fewer observers/monitors deploy on standard sector trips, then the exemption undermines our ability to meet required coverage levels and increases the uncertainty of discard rates calculated for unobserved standard sector trips. Therefore, in fishing year 2013, we required sectors to pay for 100 percent of the at-sea cost for a monitor on all redfish exemption trips, which resulted in sectors not taking a redfish trip that fishing year.

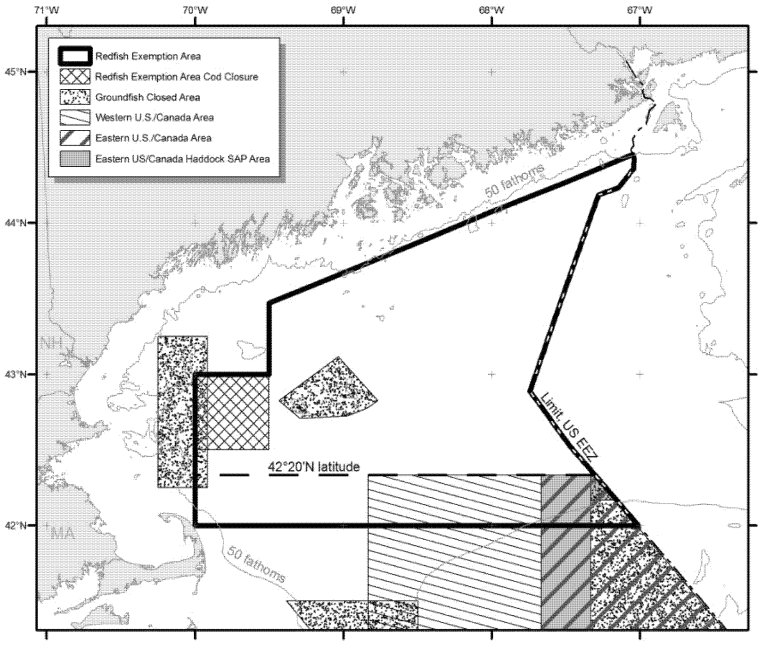
For fishing year 2014, we granted an exemption that allowed vessels to use a 6-inch (15.2-cm) or larger mesh codend to target redfish when fishing in the Redfish Exemption Area. The vessels participating in the redfish fishery in fishing year 2014 were subject to the same NEFOP and ASM target coverage as standard groundfish trips (26 percent). Vessels could fish with the regulated mesh nets (6.5-inch (16.5-cm) codends or larger) and with the 6.0-inch (15.2-cm) mesh codends on the same trip; however, for all trips (by sector, by month) declaring this exemption, we monitored landings for the entire trip to determine if the vessel had met the 80-percent redfish catch threshold and the 5-percent discard threshold.

Following our granting of the exemption in fishing year 2014, sectors indicated that an 80-percent redfish catch threshold, based on REDNET data collected using a 4.5-inch (11.4-cm) mesh codend, is not appropriate for all mesh sizes (*i.e.,* as mesh size increases, the efficiency of catching redfish decreases). Additionally, given the average landed value of redfish, they indicated that they do not consider it economically viable to have an offload comprised of 80 percent redfish. Therefore, as of January 2015, few trips have been taken under this exemption, because, according to sectors, they cannot effectively or profitably target redfish to meet the 80-percent threshold.

For fishing years 2015 and 2016, we proposed granting the sectors' request to use a 5.5-inch (14.0-cm) mesh codend when fishing in the redfish exemption, along with other changes from the previous years' exemption that provide operational flexibility while also seeking to ensure consistency with the FMP's mortality, selectivity, and spawning protection objectives. A vessel would have the option to fish the first portion of a trip with current legal codend mesh size (6.5 inches; 16.5 cm), and then switch to a codend no smaller than 5.5 inches (14.0 cm) for the redfish portion of their trip. Allowing sectors to legally target groundfish on the first portion of the trip would provide flexibility and would address the sector's concern regarding profitability. In addition, the sectors requested a 50-percent catch threshold, which would only apply to the second half of the trip. The sectors argue that this threshold is more appropriate for a 5.5-inch (14.0-cm) codend, as data from Component 3 of the REDNET report (Pol and He 2013) indicates that as the codend mesh size increases from 4.5 inches (11.4 cm) to 5.5 inches (14.0 cm), selectivity decreases, making it more difficult for vessels to catch only redfish. However, the lower 50-percent threshold would allow greater catch of other regulated groundfish species with small mesh, which could result in higher discards or targeting of groundfish with small mesh. We are proposing to address this in part by implementing reporting requirements to facilitate monitoring and increased coordination with enforcement. If we detect vessels targeting non-redfish stocks, particularly stocks of concern, the RA retains the right to rescind the exemption. The 5-percent discard threshold for all groundfish, including redfish, would still apply on the redfish portion of observed trips.

Another way of addressing our concern for incidental catch and bycatch of groundfish, and in particular due to our concern for GOM cod, we proposed to grant a modified redfish exemption area from 2014 (see Figure 2).

**Figure 2. 2015 and 2016 Redfish Exemption Area**




The Redfish Exemption Area would be bounded on the east by the U.S.-Canada Maritime Boundary, and bounded on the north, west, and south by the following coordinates, connected in the order listed by straight lines:

| Point | N. Lat. | W. Long. | Note |
|---|---|---|---|
| A ..... | 44°27.25′ | 67°02.75′ | |
| B ..... | 44°16.25′ | 67°30.00′ | |
| C ..... | 44°04.50′ | 68°00.00′ | |
| D ..... | 43°52.25′ | 68°30.00′ | |
| E ..... | 43°40.25′ | 69°00.00′ | |
| F ..... | 43°28.25′ | 69°30.00′ | |
| G ..... | 43°00.00′ | 69°30.00′ | |
| H ..... | 43°00.00′ | 70°00.00′ | |
| I ..... | 42°00.00′ | 70°00.00′ | |
| J ..... | 42°00.00′ | (67°00.63′) | (1) |

[1] The intersection of 42°00′ N. latitude and the U.S.-Canada Maritime Boundary, approximate longitude in parentheses.

We worked with the sectors and modified the redfish exemption area to exclude block 138 for the entire fishing year, and allow only seasonal access to block 131. Sector vessels would not be allowed to use the redfish exemption in block 131 in February and March. We based this decision on the closures implemented by the November 2014 interim action taken for the protection of cod; areas 138 and 131 were the only areas closed by the interim action that overlapped with the fishing year 2014 redfish exemption area. These areas are known to have higher levels of GOM cod catch and/or spawning activity, and we proposed to close them to avoid interaction with and bycatch of GOM cod. Additionally, area 138 has historically had very little redfish catch; therefore, the exclusion of this area should not limit sectors from targeting redfish. The area is bounded on the east, north, west, and south by the following coordinates, connected by straight lines in the order listed:

| Point | N. Lat. | W. Long. |
|---|---|---|
| G ..... | 43°00.00′ | 69°30.00′ |
| H ..... | 43°00.00′ | 70°00.00′ |
| K ..... | 42°30.00′ | 70°00.00′ |
| L ..... | 42°30.00′ | 69°30.00′ |
| G ..... | 43°00.00′ | 69°30.00′ |

Vessels must declare their trip in the PTNS under standard requirements, but there are no additional monitoring requirements above the target coverage for the groundfish fishery. Prior to leaving the dock, any vessel that intends to use the redfish exemption on a trip must declare so through the VMS trip start hail by checking the box next to ''Redfish Trip'' under sector exemptions. This notification must be made if the vessel intends to use a 5.5-inch (14.0-cm) codend or larger to target redfish on any portion of the trip.

Any vessel declaring this exemption must submit catch reports via VMS each day for the entire trip. For the first portion of the trip, a vessel may fish using a 6.0-inch (15.2-cm) mesh codend with selective gear in the GB BSA (current mesh flexibility allowed from Council exemption est. in 2010) or 6.5-inch (16.5-cm) mesh codend in any BSA, including the GOM. Any sub-legal codend must be stowed below deck for this entire portion of the trip. Catch thresholds do not apply to this portion of the trip.

When a vessel switches its codend to target redfish, it must first transit to the Redfish Exemption Area. Once the vessel is in the Redfish Exemption Area, it must declare via VMS that it is switching to the 5.5-inch (14.0-cm) mesh codend (or larger) and will be conducting the remainder of its fishing activity exclusively in the Redfish Exemption Area. The vessel can then retrieve the 5.5-inch (14.0-cm) mesh codend from below deck and begin using it. All fishing activity for the remainder of the trip must occur in the Redfish Exemption area. For this portion of the trip, at least 50 percent of the total allocated groundfish kept must be redfish, and on observed trips, no more than 5 percent of all groundfish, including redfish, may be discarded. The vessel must also submit a final catch report and a Trip End Hail via VMS at the end of the trip to facilitate dockside enforcement. We will use these thresholds and catch data or other information to determine if this sector exemption should be revoked.

There are enforcment concerns associated with the additional flexibility this exemption provides. Specifically, enforcing different mesh size restrictions on different portions of a single fishing trip could be challenging at sea. We are concerned about the potential for vessels to misreport the mesh size used when other groundfish are caught on the redfish portion of the

trip. Misreporting could help a vessel avoid falling below the required threshold.

Additionally, we remain concerned about vessels catching groundfish, including their bycatch of juvenile fish and incidental catch or bycatch of GOM cod, which could potentially cause them to exceed the discard threshold of 5 percent, in the Redfish Exemption Area when fishing with codend mesh sized nets smaller than the GOM regulated mesh size of 6.5 inches (16.5 cm). The 50-percent catch threshold is meant to reflect the likely proportion of redfish catch while using a 5.5-inch (14.0-cm) mesh codend, based on the results of Component 3 of REDNET. When determining the threshold, we also considered trips from a portion of the 2012 fishing year, when vessels were allowed to use as small as a 4.5-inch mesh codend. Based on this data and our analysis of use of the exemption, sector needs, and the FMP's goals and objectives, we have set a threshold to provide an incentive to target redfish while balancing the incidental catch of other allocated stocks in a mixed species fishery.

We remain concerned, however, that the exemption could allow sectors to target groundfish when fishing with a smaller codend or increase discards that would likely go unreported, which could undermine the protections of the 5-percent bycatch threshold. Because of these concerns, we intend to monitor use of the exemption closely. We intend to watch whether vessels are using the exemption when assigned an observer or ASM, or only using it when unobserved, which would affect our ability to monitor the exemption. Additionally, if a vessel does not submit daily catch reports or the required declaration when switching to the redfish portion of the trip, we may not be able to adequately monitor the exemption. If issues such as these arise, or if monitoring reveals that trips are having higher than expected catch of other groundfish, we may notify sectors so that they can work with their vessels to change fishing behavior or comply with the exemption requirements. However, as previously stated, the RA retains authority to rescind of this exemption, if it is needed.

We received four comments related to the redfish exemption, all of which were supportive of the exemption as it was described in the proposed rule. One industry member commented that a 5.5-inch (14.0-cm) codend is the appropriate mesh size to target redfish, and that the exemption will redirect effort away from GOM cod and onto redfish, because the redfish exemption area lies offshore, where there has been lower catch of GOM cod. One sector-related group commented in support of the proposed catch thresholds, stating that they adequately reflected the catch composition when using a 5.5-inch (14.0-cm) codend. This group also supported modifications intended to minimize interactions with GOM cod. An industry group supported strict monitoring of the exemption. We have provided a more detailed response to these comments in the Comments and Responses Section below.

In previous years, we have granted versions of the redfish exemption that were more restrictive. This was to ensure that sector vessels were effectively targeting only redfish. However, during the development of the fishing years 2015 and 2016 exemption, we heard that these requirements were too onerous and have discouraged use of the exemption. For fishing years 2015 and 2016, we are granting the exemption with modifications as we proposed. We are seeking to strike a balance between allowing access to an underutilized, healthy stock and meeting objectives to prevent overfishing. As previously discussed, we intend to monitor this exemption, and retain the authority to rescind the exemption if thresholds are not being met.

**Denied Fishing Years 2015 and 2016 Exemptions Requests**

In addition to the 19 exemptions granted in this final rule, we are denying three other exemption requests for fishing years 2015 and 2016. The GOM haddock sink gillnet exemption was previously rejected, continues to be of concern, and no new information has been submitted that justifies granting it. Regarding the VMS powerdown exemption, sectors demonstrated a lack of compliance in previous years. The requested 2014 fishing year version of the redfish exemption was too similar to the 2015 and 2016 fishing year redfish exemption that is granted by this rule. Based on this, we are denying these exemptions in this final rule.

**Exemption That May Be Considered in a Separate Action**

*Prohibition on Groundfish Trips in Closed Areas (CA) I and II*

In fishing year 2013, we denied an exemption that would have allowed sector vessels restricted access to portions of CAs I and II, provided each trip carried an industry-funded ASM. When we proposed allowing sector access to these areas, we announced that we did not have funding to pay for monitoring the additional trips for exemptions requiring a 100-percent coverage level. Industry members indicated that it was too expensive to participate in the exemption given the requirement to pay for a monitor on every trip. This, in combination with extensive comments opposing access to these areas to protect depleted stocks and our concern about the impacts on depleted stocks such as GB cod and GB yellowtail flounder, resulted in disapproval. For a detailed description of the exemption request and justifications for disapproval, see the final rule (78 FR 41772, December 16, 2013).

For fishing year 2014, we remained unable to fund monitoring costs for exemptions requiring a 100-percent coverage level. In addition, we had some concerns about funding and administering the shore-side portion of any monitoring program for an exemption that requires additional ASM, such as the exemption to access CAs I and II. However, we authorized two EFPs to gather catch data from CAs I and II, one in coordination with the Northeast Fisheries Science Center, the other with members of the industry. Results from these EFPs could better inform us, the industry, and the public, regarding the economic efficacy of accessing these CAs, while providing information specific to bycatch of depleted stocks. Trips taken under these EFPs are attempting to address the following questions: (1) Could enough fish be caught to adequately offset the industry's additional expense of having an ASM on board, and (2) could catch of groundfish stocks of concern be addressed?

The two authorized EFPs have allowed access to participating vessels into the same portions of CAs I and II that were originally proposed for access to sectors. Vessels using the EFPs are required to use specialized trawl gear to reduce impacts on flounder species, are restricted seasonally to avoid spawning fish, and must adhere to an agreement between the lobster and groundfish fishery in CA II to avoid gear conflicts. One of the two approved EFPs is still ongoing. Upon review of the EFP results, we will consider potential access to these areas through a separate action.

**Additional Sector Operations Plan Provisions**

*Inshore GOM Restrictions*

Several sectors have proposed an operations plan provision to limit and more accurately document a vessel's behavior when fishing in what they

consider the inshore portion of the GOM BSA, or the area to the west of 70°15′ W. long. We approve this provision, but note that a sector may elect to remove this provision in the final version of its operations plan.

Under this provision, a vessel that is carrying an observer or at-sea monitor would remain free to fish in all areas, including the inshore GOM area, without restriction. If a vessel is not carrying an observer or at-sea monitor and fishes any part of its trip in the GOM west of 70°15′ W. long., the vessel would be prohibited from fishing outside of the GOM BSA. Also, if a vessel is not carrying an observer or at-sea monitor and fishes any part of its trip outside the GOM BSA, this provision would prohibit a vessel from fishing west of 70°15′ W. long. within the GOM BSA. The approved provision includes a requirement for a vessel to declare whether it intends to fish in the inshore GOM area through the trip start hail using its VMS unit prior to departure. We provide sector managers with the ability to monitor this provision through the Sector Information Management Module (SIMM), a Web site where we also provide roster, trip, discard, and observer information to sector managers. A sector vessel may use a federally funded NEFOP observer or at-sea monitor on these trips because we do not believe it will create bias in coverage or discard estimates, as fishing behavior is not expected to change as a result of this provision.

*Prohibition on a Vessel Hauling Another Vessel's Trap Gear To Target Groundfish*

Several sectors have requested a provision to allow a vessel to haul another vessel's fish trap gear, similar to the current exemptions that allow a vessel to haul another vessel's gillnet gear or hook gear. These exemptions have generally been referred to as ''community'' gear exemptions. Regulations at § 648.84(a) require a vessel to mark all bottom-tending fixed gear, which would include fish trap gear used to target groundfish. To facilitate enforcement of that regulation, we are requiring that any community fish trap gear be tagged by each vessel that plans on hauling the gear, similar to how this provision was implemented in fishing year 2014. This allows one vessel to deploy the trap gear and another vessel to haul the trap gear, provided both vessels tag the gear prior to deployment. This requirement will be captured in the sector's operations plan to provide the opportunity for the sector to monitor the use of this provision and ensure that the Office of Law Enforcement (OLE) and the U.S. Coast Guard can enforce the provision.

**At-Sea Monitoring Proposals**

For fishing years 2015 and 2016, each sector is required to develop and fund an ASM program that must be reviewed and approved by NMFS. In the event that a proposed ASM program could not be approved, all sectors were asked to include an option to use the current NMFS-designed ASM program as a back-up. Sustainable Harvest Sectors 1 and 3, GB Cod Fixed Gear Sector, Northeast Coastal Communities Sector, and Maine Coast Community Sector have proposed to use the ASM program that was developed and used for fishing years 2010–2014. We approve this program for these sectors because we believe the existing program to be consistent with goals and objectives of monitoring, and with regulatory requirements. NEFS IV has not included provisions for an ASM program because the sector operates as a private permit bank and explicitly prohibits fishing.

We approve the ASM programs proposed by the remaining 12 sectors, NEFS I–XIII (excluding NEFS IV). These programs state that they will: Contract with a NMFS-approved ASM provider; meet the specified coverage level; and utilize the PTNS for random selection of monitored trips and notification to providers. In addition, these ASM programs include detailed protocols for waivers, incident reporting, and safety requirements. We have determined that the programs are consistent with the goals and objectives of at-sea monitoring, and with the regulatory requirements.

Although the current regulations require a sector to fund its costs for its ASM program beginning in fishing year 2012, we funded industry's ASM costs in fishing years 2013 and 2014. Because of SBRM funding requirements and budgetary uncertainty, it is unclear if the Agency will have money to fund industry's ASM costs for the entire fishing year 2015, but at this point, we anticipate industry taking on the responsibility for their at-sea monitoring costs during fishing year 2015. As mentioned previously, our ability to fund our portion of costs for ASM coverage above SBRM coverage levels for the entire 2015 and 2016 fishing years is also not known at this time. Currently, funding for our portion of ASM costs is expected to expire before the end of the 2015 fishing year. If we have insufficient funding available for our portion of coverage costs beyond that time, we may need to consider other measures, including emergency action, to allow sectors to continue fishing while still ensuring that we can adequately monitor sector catch for management purposes. Additional information on funding and implementation of ASM for fishing year 2015 will be provided as it becomes available.

**Comments and Responses**

We received a total of nine comments from: Associated Fisheries of Maine (AFM), Center for Biological Diversity, NEFS V, NEFS XI, Northeast Sector Service Network (NESSN), Oceana, SHS, and two members of the fishing industry. We received five comments from members of the fishing industry that were not relevant to the sector operations plans or exemptions. Only comments that were applicable to the proposed measures, including the analyses used to support these measures, are responded to below.

*Re-Authorization of Sector Exemptions Previously Granted (1–16)*

*Comment 1:* AFM and NESSN support the approval of exemptions as proposed. NEFS V and NEFS XI specifically support the exemptions from the 120-day block and the 20-day spawning block requirements, and NEFS V asserts that these exemptions should apply to the entire groundfish fishery. NEFS XI supports the exemption from the prohibition on a vessel hauling another vessel's gillnet gear.

*Response:* We have granted the 16 exemptions as proposed.

*Comment 2:* NESSN commented on our noted concern about the five proposed exemptions that apply in the GOM and their effect on GOM cod, stating that none of these exemptions are proposed solely for the GOM, and that it is unclear what the Agency would hope to accomplish by revoking them.

*Response:* These five exemptions apply to or could be used in the GOM. Because GOM cod is at very low levels, we asked the public to comment if there was any information that might suggest these exemptions could negatively affect GOM cod. We received no comments with information suggesting that, and therefore we are granting these exemptions for fishing years 2015 and 2016.

*Exemption From the Prohibition on Combining Small Mesh Exempted Fishing With a Sector Trip (17)*

*Comment 3:* NESSN and NEFS V support NMFS' proposal to grant this exemption as modified from fishing year 2014, specifically expanding the exemption area 15′ northward.

*Response:* We have granted this exemption as proposed. As noted in the preamble, this expansion will allow for greater opportunities for sector vessels to target small-mesh species. However, we remain concerned about vessels potentially catching groundfish, including bycatch of juvenile fish, in the requested exemption area with small-mesh nets, and therefore will continue to closely monitor catch from these exempted trips.

*Exemption From Number of Gillnets for Day Gillnet Vessels (18)*

*Comment 4:* Oceana commented in support of NMFS' proposal to deny this exemption in GOM, but urged NMFS to deny the exemption for other broad stock areas and all vessel categories. Oceana stated that the use of anchored sink gillnets poses a serious threat to the effective management of the fishery and the recovery of overfished stocks. They suggested several measures to control the use of gillnets, including revising the Vessel Trip Report regulations and limiting gear configuration and soak times.

NESSN and NEFS XI supported NMFS' proposal to grant this exemption in GB and SNE/MA, but disagree with the proposal to deny it for GOM. They suggested granting the exemption for the GOM with restrictions on certain blocks, as was approved in past years, or with additional modifications for the 2015 fishing year. They referenced the constraints already placed on sectors by low ACLs and resulting sector allocations. They state that with such a low GOM cod ACL, Day gillnet vessels will already be strategizing on how to avoid catching cod, and therefore do not need further limits on the amount of gear they can use. NESSN urged NMFS to work with the sectors to find a workable alternative to denying this exemption in the GOM.

*Response:* As discussed in the preamble, the exemption from the number of gillnets for Day gillnet vessels is granted in the GB, SNE, and MA RMAs, but is denied in the GOM. We agree with Oceana's comment and disagree with the sector organizations concerning the GOM: The condition of the GOM cod stock warrants additional protective measures in the GOM. Framework 53 sets an acceptable biological catch (ABC) that is well below the estimate of incidental catch of GOM cod that occurred in fishing year 2013. The denial of these exemptions are expected to help minimize incidental catch or bycatch of GOM cod in gillnets, and is intended to serve as a complement to the measures taken in Framework 53. Data in the EA accompanying this rule indicate that, between 2009 and 2012, the number of gillnet trips fluctuated but generally fell, the amount of catch from gillnet gear decreased, and the number of gillnet geardays (used as a proxy for effort) increased. Between 2009 and 2012, sector gillnet vessels were not operating more efficiently. For 2013, the last year for which we have data, trips, catch and geardays for gillnet gear all decreased. At this time, it is unknown if this more recent decrease in effort is a trend. Therefore, we have denied this exemption in the GOM as an additional measure to help sectors avoid GOM cod.

The 2014 interim action for GOM cod originally rescinded this exemption for fishing year 2014 for the GOM RMA. In that rule, we also suspended the GOM Rolling Closures and implemented seasonal interim closures intended to better protect spawning aggregations of GOM cod. We noted our concern that ''continuing the exemption could cause barriers of gillnets along the boundaries of closed areas that would otherwise catch cod going into or coming out of the closed areas.'' As a result, we revoked the exemption as a discrete and effective measure that could reduce the overall mortality of GOM cod. Framework 53 to the NE Multispecies FMP removes the GOM Rolling Closures, and permanently replaces them with GOM cod closures, which are intended to protect spawning GOM cod, reduce fishing mortality on GOM cod, and provide additional fishing opportunities for groundfish vessels to target healthy groundfish stocks. We remain concerned that granting the exemption in the GOM could continue to contribute to or cause barriers of gillnets along these discrete closures which were intended to protect spawning. As a result, we have denied the exemption in the GOM.

Oceana also suggested several measures to control and monitor the use of gillnet gear. At this time, we do not believe it is necessary to implement additional requirements on gillnet vessels. Through the sector system, sector managers and NMFS are able to monitor the catch of all species in a timely manner. Further, regulations at § 648.87(b)(1)(ii) require all vessels in a sector to cease fishing operations in a stock area once the sector has harvested its allocation for a particular stock. This requirement has been sufficient to ensure that sectors remain within their quota. Therefore, additional measures are not necessary at this time and are outside of the scope of this action.

Oceana further urged NMFS to deny the exemption from the number of gillnets for Day gillnet vessels in all areas and for all vessel categories. Denying this exemption in the GOM is intended to help avoid incidental catch of GOM cod. Given the low GOM cod ACL approved as part of Framework 53, as well as other measures, we expect that vessels will not target GOM cod, but will instead catch it as incidental catch while targeting other groundfish stocks. This exemption is specific to Day gillnet vessels, which are allowed to leave gear in the water untended, which increases effort that may result in additional incidental catch. Limiting the number of gillnets is expected to reduce incidental catch of GOM cod.

At this time, we do not believe it is necessary to deny this exemption in other RMAs. While groundfish stocks in the other RMAs are overfished or overfishing is occurring, those stocks are in rebuilding programs and have ACLs that may support directed fisheries. Also, expanding the reduction in gillnet effort to all vessel categories is beyond the scope of this action and would require Council action. Therefore, denying this exemption in other RMAs is not warranted at this time.

NESSN and NEFS XI urged NMFS to work with the sectors to find a workable alternative to denying this exemption in the GOM. As discussed below, one sector took a proactive approach to managing their GOM cod quota, by including fishing restrictions intended to help members avoid concentrations of GOM cod. We would welcome proposals from other sectors, and will work with sectors to develop approvable measures for their operations plans. If these measures are sufficient, we could consider granting this exemption in the GOM. Additionally, if sectors do not wish to develop such measures, its member vessels could elect to operate as Trip gillnet vessels. Trip gillnet vessels are not restricted to a maximum number of nets.

*Exemption From the 6.5-Inch (16.5-cm) Mesh Size for Directed Redfish Trips (19)*

*Comment 5:* AFM, NESSN, and two members of the industry commented in support of this exemption. One industry member commented that this exemption will redirect effort away from GOM cod and onto redfish, which he describes as underutilized. That industry member also stated that the proposed 5.5-inch (14.0-cm) mesh codend is the correct size for targeting redfish. AFM and an industry member both commented in support of the flexibility that the exemption provides. AFM requested that NMFS provide sectors with a detailed description of all requirements that must be met to use the exemption.

AFM supports strict monitoring, and an industry member commented in support of not requiring industry-funded at-sea monitoring coverage with this exemption. NESSN commented with support for catch thresholds, and stated that the chosen thresholds adequately reflect the likely proportion of redfish catch while using a 5.5-inch (14.0-cm) mesh codend. They agreed with the adjustment to the exemption area out of concern for GOM cod, and feel that the requirements of the exemption adequately address OLE's concerns. NESSN also commented that the Agency can revoke the exemption mid-season if sectors are not meeting the requirements of the exemption.

*Response:* In previous years, we have granted versions of the redfish exemption that were more restrictive. To ensure that sector vessels using the exemption effectively targeted redfish, did not target other species with a smaller mesh, and attempted to avoid catching sub-legal or juvenile groundfish, we placed additional requirements on sectors when using this exemption such as 100-percent observer coverage, redfish catch thresholds of 80 percent, and higher mesh sizes. The intent of these exemptions has always been to allow vessels to target redfish while balancing the FMP's mortality, selectivity, and spawning protection objectives; however, we have heard from the sectors in the development of the fishing years 2015 and 2016 exemption that these requirements are too onerous, and have discouraged the use of the exemption.

This year, we are changing some of the requirements from past years. It is our hope that this exemption, which allows vessels to use a smaller mesh size (5.5 inches; 14.0 cm), fish on a combined groundfish/redfish trip, and have a lower target of redfish (50 percent), will result in more effort in the redfish fishery, while still meeting FMP's mortality, selectivity, and spawning protection objectives.

We believe that this exemption will help direct effort onto redfish, a healthy stock. The redfish exemption area lies offshore, where there has been lower catch of GOM cod, and therefore we agree with the comment that this exemption will redirect effort away from GOM cod. As mentioned above, Framework 53 has set an ABC below the 2013 incidental catch estimates, and so sector vessels will already be attempting to avoid the catch of GOM cod. To assist with this, and because of our continued concern for GOM cod, we removed two blocks (one for the entire year, one seasonally) from the 2014 exemption area. These two blocks are known to have higher levels of GOM cod catch and/or spawning activity and removing them from the exemption area will further reduce the likelihood of GOM cod interactions for vessels using the exemption.

We intend to monitor this exemption closely, with increased coordination with enforcement, to ensure that it is not increasing the catch of undersized or juvenile groundfish or significantly increasing incidental catch of GOM cod. We will be reviewing catch data, observer data, and fishing practices closely. If we determine at any time that this exemption is causing concerning levels of bycatch of undersized groundfish, incidental catch of GOM cod, or fishing practices that adversely affect ASM, we intend to work with sector managers to correct the problem; however, the RA retains the authority to rescind approval of this exemption as needed. Monitoring will also provide us with more data on which we can refine future decisions regarding the optimal mesh size and threshold for a sustainable redfish fishery.

Having learned in past years that additional monitoring coverage as part of this exemption leads to decreased use by the fishing industry, we have not proposed additional monitoring requirements for fishing years 2015 and 2016. The observer coverage rate for sectors, including vessels fishing under this exemption, will be 24 percent. The NEFOP portion is 4 percent; the ASM portion is estimated to be 20 percent. Sectors will likely be required to pay for the sea day cost of ASM for part of the 2015 fishing year.

We will provide sectors who have selected the exemption with the full requirements for using the exemption through their operations plan and LOAs before the beginning of the fishing year. This will include the correct process for declaring a redfish trip via PTNS and VMS, reporting requirements, gear use and stowage requirements, and area and time constraints.

*GOM Haddock Sink Gillnet Mesh Exemption*

*Comment 6:* NESSN and NEFS XI commented that they disagree with NMFS' proposal to deny the GOM Haddock Sink Gillnet Mesh Exemption. They state that the exemption would allow them to selectively target GOM haddock, a stock which is rebuilding, with minimal catch of GOM cod.

*Response:* We agree that the status of GOM haddock has improved. We released an updated stock assessment for GOM haddock in October 2014, which indicated that GOM haddock is no longer overfished and overfishing is not occurring. This change was due primarily to the addition of three more years of fishery and survey data, and to the very strong 2010 year class of GOM haddock. As a result we published an emergency rule (79 FR 67090) on November 12, 2014, increasing the commercial sub-ACL.

However, while the GOM haddock stock is improving, the GOM cod stock is at a critically low level. In the proposed rule, we proposed to deny the GOM Haddock Sink Gillnet Exemption due to our concern for GOM cod. We noted our concern that continuous fishing of gillnets left in the water and the potential to disrupt spawning when GOM cod are caught. We also noted that using nets smaller than the minimum size may affect GOM cod mortality. Amendment 16 to the NE Multispecies FMP provided in-depth analysis of this exemption, when it proposed and analyzed a fishery-wide pilot program. It noted that ''sink gillnets are also effective at targeting cod and pollock, and this measure may also affect mortality of these two stocks . . . As can be seen in the cod selectivity curve (Figure 132), 6 inch gillnets will select smaller cod than 6.5 inch gillnets,'' but noted that the average was still larger than the minimum size. This analysis, however, was done at a time when the GOM cod stock was under a successful rebuilding program. As previously discussed in the response to Comment 4, any additional pressure on the GOM cod stock could severely affect its ability to rebuild from critically low levels. Further, it would be inconsistent with our approval of the GOM cod ACL amount below the 2013 incidental catch level and the GOM cod protection closures in Framework 53 that are designed to further reduce GOM cod mortality. Therefore, we have denied this exemption for fishing years 2015 and 2016.

*VMS Powerdown*

*Comment 7:* NEFS XI commented that they do not support NMFS' proposal to deny this exemption. They state that if the exemption is not approved, compliance with the requirement to keep VMS powered will still be an issue. NEFS XI recommended more robust outreach directly to the industry on the part of NMFS to increase compliance, rather than through sector managers.

*Response:* VMS is a tool that allows enforcement to monitor compliance, track violators, and provide evidence to support enforcement actions. The system uses satellite-based communications from on-board units, which send position reports that

include vessel identification, time, date, and location, and are mapped and displayed on the end user's computer screen. NMFS uses VMS to monitor the location and movement of commercial fishing vessels. All active sector vessels are required to use VMS. Each unit typically sends position reports once an hour. Within the groundfish fishery, it is a critical tool for monitoring the fishery. Non-compliance with VMS requirements decreases our confidence in our ability to adequately monitor the fishery.

We first granted an exemption allowing sector vessels the ability to power down while at the dock beginning in fishing year 2011. Beginning in fishing year 2012, OLE recognized a lack of compliance with the requirements of this exemption, such as not sending the VMS powerdown code before turning off the VMS unit, not turning on the VMS unit before leaving the dock, or turning off the VMS unit before docking. We raised our concerns over compliance with managers on our monthly sector manager conference calls. Seeing that compliance had not improved, OLE worked to identify sector members that were out of compliance with this exemption. We provided this information to sector managers and requested their assistance in reaching out to their members. At that time, we informed sector managers that if compliance did not improve during fishing year 2013, we would reconsider approving the exemption for fishing year 2015. After receiving the request for this exemption for fishing year 2015, we re-examined compliance with the exemption, updated with available data from fishing year 2014, and found that compliance had not improved. Therefore, we are denying the exemption for fishing year 2015.

We have heard the concerns raised by NEFS XI and others regarding the disapproval of the VMS powerdown exemption. NEFS XI explained that some of its members ''do not have the ability to maintain their VMS systems while in port as these vessels do not have access to shore power'' which may lead to VMS shut down. We understand this inconvenience, and will work with sector vessels, as appropriate, when this occurs. We note, however, that vessels successfully complied with this requirement for many years prior to our granting these exemptions. Additionally, sectors are welcome to request, and we may consider, this exemption at a future date. However, we would require sectors to demonstrate a clear plan for maintaining a high level of compliance with the exemption's requirements.

*At-Sea Monitoring*

*Comment 8:* Oceana commented that the 24-percent monitoring level is too low, asserting that this level adds clear incentives to misreport discarded fish and create harmful bias. They contend that the agency must require monitoring levels that preclude behavioral differences between observed and unobserved trips, or else expand the use of uncertainty buffers to account for the low monitoring levels. The Center for Biological Diversity commented that 100-percent observer coverage is necessary.

*Response:* Similar comments have been received on previous fishing years' sector operations rules, and the responses can be found in the published final rules, most recently the 2014 Sector Operations Final Rule (79 FR 23278; April 28, 2014) and the 2013 Sector Operations Final Rule (78 FR 25591; May 2, 2013).

We have determined that 24-percent observer coverage of sector trips is sufficient, to the extent practicable in light of Magnuson-Stevens Act requirements, to reliably estimate catch for purposes of monitoring sector ACEs and ACLs for groundfish stocks. This determination is based in part on the statistical sufficiency of the level of coverage as summarized in more detail at: *http://www.greateratlantic.fisheries.noaa.gov/ro/fso/reports/Sectors/ASM/FY2015_Multispecies_Sector_ASM_Requirements_Summary.pdf.* Our determination also incorporates how data and information are collected and analyzed, including obligations on sectors to self-monitor and self-report, which is linked to agency monitoring. For the most part, these commenters have generally asserted that this system and level of monitoring is not adequate without providing any specific justification or information to support their assertion.

Amendment 16 specified that ASM coverage levels should be less than 100 percent, which requires that the discard portion of catch, and thus total catch, be an estimate. Amendment 16 also specified that the ASM coverage levels should achieve a 30-percent CV. The level of observer coverage, ultimately, should provide confidence that the overall catch estimate is accurate enough to ensure that sector fishing activities are consistent with National Standard 1 requirements to prevent overfishing while achieving on a continuing basis optimum yield from each fishery. To that end, significant additional uncertainty buffers are established in the setting of ACLs that help make up for any lack of absolute precision and accuracy in estimating overall catch by sector vessels.

In developing Amendment 16, the Council anticipated that NEFOP might not have sufficient resources to fund sector catch monitoring, so Amendment 16 specified that starting in fishing year 2012 sectors would be required to develop an industry-funded ASM program to monitor sector catch. The NEFOP program provides at-sea observers, and the coverage provided to sectors by that program partially satisfies the sector-specific ASM provision. Collectively, the at-sea coverage provided by the ASM and NEFOP programs is providing more data for quota management and assessment science than was available to NMFS prior to implementation of Amendment 16.

On February 18, 2014, in *Oceana, Inc.* v. *Pritzker,* 1:13–cv–00770 (D.D.C. 2014), the Court upheld our use of a 30-percent CV standard to set ASM coverage levels. In addition to upholding our determination of sufficient coverage levels, the Court noted that the ASM program is not the sole method of monitoring compliance with ACLs, there are many reporting requirements that vessels adhere to, and there are strong incentives for vessels to report accurately because each sector is held jointly and severally liable for overages and misreporting of catch and bycatch.

*Comment 9:* Oceana commented that at-sea monitoring coverage levels should be set at the vessel level of stratification. They state that this is because sector operations plans specify that sector members are to harvest an amount of fish equal to the amount each member's permit contributed to the sector.

*Response:* Amendment 16, developed by the Council and approved by NMFS, allows each sector to determine which vessels will actively fish and how best to harvest its allocation, including decisions regarding consolidation. Amendment 16 did not place restrictions on a sector's decision of how to allocate ACE to its members. Thus, each sector is free to determine how ACE will be assigned to its member vessels. For fishing years 2015 and 2016, sectors generally have elected to assign each member the portion of the sector's ACE that it brings to a sector. This is typically based on each permit's contribution to the sector's ACE, as modified by the sector. In practice, in some years, sector members have opted to pool some stock's ACEs for use by all

members. This does not mark a change from previous fishing years.

Additionally, Amendment 16 specified a performance standard that coverage levels must be sufficient to at least meet the coefficient of variation (CV) specified in SBRM (a CV of 30 percent), but was unclear as to what level the CV standard is to be applied to—discard estimates at the stock level for all sectors, or for each combination of sector and stock. Framework 48 clarified that the CV standard is intended to apply to discard estimates at the overall stock level for all sectors combined. As discussed in NMFS' response to comments on Framework 48, the Council and NMFS have determined this level is sufficient as a minimum standard for monitoring sector ACEs, consistent with the goals of Amendment 16 and the FMP.

*GOM Cod*

*Comment 10:* AFM and SHS commented on the ''Gulf of Maine Cod Program,'' which contains voluntary measures to help those sectors avoid concentration of GOM cod, and that SHS 1 and 3 have created and adopted.

*Response:* We appreciate the Sustainable Harvest Sectors' efforts to reduce the fishing impacts on GOM cod. We understand that this program is voluntary and only applies to SHS 1 and 3. We also understand that SHS 1 and 3 can discontinue the program as they see fit, but the sectors will be required to request an operations plan amendment if they choose to do so.

*Two-Year Operations Plans*

*Comment 11:* NESSN commented in support of the transition to 2-year operations plans. They hope streamlining this process will allow for ''more effective proactive communication and collaboration for tools that foster effective sector management, such as sector exemptions.'' They noted the importance of maintaining flexibility in the second year of operations. Specifically, NESSN highlighted the need for sectors to request and develop exemptions and for members to re-evaluate their enrollment decision prior to May 1, 2016.

*Response:* We are approving sector operations plans for fishing years 2015 and 2016. This is an important step toward streamlining the sector approval process. We share NESSN's hope that approving operations plan for 2 years will allow sectors and NMFS to work together on the development of exemptions and other proactive measures to address emerging issues. We also hope that we can collaborate with the sectors to further streamline sector requirements.

As stated in the proposed rule, we will allow permit holders the opportunity to join, change, or drop out of sectors for fishing year 2016. Consistent with past years, we will distribute fishing year 2016 PSC letters to permit holders, set 2016 roster deadlines, and notify permit holders and sector managers of the fishing year 2016 deadlines. Once sectors submit their roster information, we will publish sector ACEs and common pool sub-ACL totals, based upon fishing year 2016 rosters.

We understand the importance of being able to request additional exemptions in the second year of operations, especially given low ACLs and other restrictive management measures approved by the Council. We encourage sectors to submit requests for new or revised exemptions at any point during fishing years 2015 and 2016. After reviewing any request, we will provide sectors with comments on their request, and work with them to develop an acceptable exemption and will grant or deny the exemption consistent with the Administrative Procedure Act. We may combine exemption requests into one or more rules, as staff resources allow.

EA

*Comment 12:* NESSN commented on the lack of analysis in the EA for the GOM Haddock Sink Gillnet Mesh exemption, stating that ''it continues to be unclear why an exemption disapproved because of stock status is not automatically reconsidered and analyzed in light of a change in stock status.''

*Response:* NMFS considered several exemption requests, but rejected them for further analysis in the EA, including the GOM Haddock Sink Gillnet Mesh exemption. In previous cases, we have considered but rejected most exemptions we denied for fishing years 2010 through 2014, unless the sectors were able to provide new information or data to support their current request. We denied this exemption, which was requested to facilitate catch of GOM haddock, in fishing years 2013 and 2014 because of the poor condition of the GOM haddock stock. While a new stock assessment found GOM haddock to be in improved condition, since then a separate assessment found GOM cod to be in poor condition. We did not update our analysis of this exemption's impact on GOM haddock in the EA for this action because we are denying the GOM Haddock Sink Gillnet Exemption in this action due to this gear's potential adverse impact on GOM cod. We recognize that the condition of stocks changes over time, and may reconsider and reanalyze this exemption in future actions based on updated stock condition for GOM cod, GOM haddock, and other stocks in the multispecies fishery. In this action, however, because of the poor condition of GOM cod requiring us to deny this exemption request, we considered but rejected this exemption from further analysis in the EA.

**Classification**

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this final rule is consistent with the NE Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This action is exempt from the procedures of Executive Order 12866 because this action contains no implementing regulations.

Because this rule relieves several restrictions, the AA finds good cause under 5 U.S.C. 553(d)(1) and (3) to waive the 30-day delay in effectiveness so that this final rule may become effective by May 1, 2015. Sector Operation Plan exemptions grant exemptions or relieve restrictions that provide operational flexibility and efficiency that help avoid short-term adverse economic impacts on NE multispecies sector vessels. When the 17 approved Sector Operations Plans become effective, sector vessels are exempted from common pool trip limits, DAS limits, and seasonal closed areas. These exemptions provide vessels with flexibility in choosing when to fish, how long to fish, what species to target, and how much catch they may land. They also relieve some gear restrictions, reporting and monitoring requirements, and provide access to additional fishing grounds through the authorization of 19 exemptions from NE multispecies regulations for fishing years 2015 and 2016. This flexibility increases efficiency and reduces costs.

In addition to relieving restrictions and granting exemptions, avoiding a delay in effectiveness prevents vessel owners from incurring significant adverse economic impacts. A delay in implementing this rule would prevent owners who joined a sector in fishing year 2015 (842 permits, accounting for 99 percent of the historical NE multispecies catch) from fishing during the delay and would diminish the advantage of the flexibility in vessel operations, thereby undermining the

intent of the rule. During any delay, sector vessels would be prohibited from fishing for groundfish. Being prohibited from fishing for up to 30 days would have a significant adverse economic impact on these vessels because vessels would be prevented from fishing in a month when sector vessels landed approximately 10 percent of several allocations, including Eastern GB cod and GB winter flounder. Further, sector vessels could only fish during this delay if they chose to fish in the common pool. Once they switched to the common pool, however, they could not return to a sector for the entire fishing year and would forego the flexibility and economic efficiency afforded by sector exemptions. Vessels choosing to fish in the common pool to avoid a 30-day delay in the beginning of their season would then forego potential increased flexibility and efficiencies for an entire fishing year. For the reasons outlined above, good cause exists to waive the otherwise applicable requirement to delay implementation of this rule for a period of 30 days.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

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

Dated: April 20, 2015.

**Eileen Sobeck,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

[FR Doc. 2015–09950 Filed 4–30–15; 8:45 am]

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 648**

**[Docket No. 150305221–5221–01]**

**RIN 0648–BE82**

## Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Groundfish Fishery; Fishing Year 2015; Recreational Management Measures

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

**ACTION:** Interim final rule; request for comments.

**SUMMARY:** This action implements a reduction to the minimum size for Gulf of Maine haddock taken in the recreational fishery. This action is necessary to ensure that the recreational catch of haddock and recreational bycatch of cod will not exceed the annual catch limits for the recreational fishery in fishing year 2015. The intended effect of this action is to reduce discards of cod and haddock by allowing recreational anglers to retain smaller haddock, which will result in anglers achieving their bag limit more quickly.

**DATES:** Effective May 1, 2015. Comments must be received by June 1, 2015.

**ADDRESSES:** You may submit comments on this document, identified by NOAA–NMFS–2015–0046, by either of the following methods:

*Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0046*
2. Click the ''Comment Now!'' icon, complete the required fields, and
3. Enter or attach your comments.

—OR—

*Mail:* Submit written comments to: John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on the fishing year 2015 Haddock Recreational Measures.''

*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).

Copies of a supplemental environmental assessment (EA) to Framework Adjustment 53 prepared by the Greater Atlantic Regional Fisheries Office (GARFO) and Northeast Fisheries Science Center and the Framework 53 EA prepared by the New England Fishery Management Council for this rulemaking are available from: John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. The Framework 53 EA and supplement are also accessible via the Internet at: *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies/.*

**FOR FURTHER INFORMATION CONTACT:** Mark Grant, Sector Policy Analyst, phone: 978–281–9145; email: *Mark.Grant@noaa.gov.*

**SUPPLEMENTARY INFORMATION:**

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### 1. Fishing Year 2015 Recreational Management Measures

The recreational fishery for Gulf of Maine (GOM) cod and haddock is managed under the Northeast Multispecies Fishery Management Plan (FMP) which has been developed by the New England Fishery Management Council and approved and implemented by NMFS. Under the FMP, specific sub-annual catch limits (ACL) for the recreational fishery are established for each fishing year for GOM cod and haddock. These sub-ACLs are a subcomponent of the overall stock catch limit for each species. The multispecies fishery opens on May 1 each year and runs through April 30 of the following calendar year. The FMP also contains accountability measures, in accordance with Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) National Standard 1 guidelines.

The accountability measures outlined in the FMP indicate that the Regional Administrator may, in consultation with the Council, modify the recreational

management measures for the upcoming fishing year to ensure that the sub-ACL is not exceeded. The provisions authorizing this action can be found in § 648.89(f)(3) of the FMP implementing regulations. Additional measures necessary to facilitate enforcement of these accountability measures, consistent with the FMP, are authorized by § 305(d) of the Magnuson-Stevens Act. Recreational catch and effort data are estimated by the Marine Recreational Information Program (MRIP), a comprehensive, multi-faceted survey system administered by NMFS. Because the recreational measures currently in place for GOM cod and haddock are not expected to constrain fishing year 2015 catch to the sub-ACL, the proactive accountability measure requires adjustment of the management measures.

A peer-reviewed bio-economic model, developed by the Northeast Fisheries Science Center, was used to estimate fishing year 2015 recreational GOM cod and haddock mortality under various combinations of minimum sizes, possession limits, and closed seasons. Even after prohibiting GOM cod possession by recreational fishermen in Framework 53 to the FMP, our model estimated that the status quo measures for GOM haddock were unlikely to constrain haddock catch or cod bycatch within the fishing year 2015 catch limits, thus requiring that we implement additional measures.

After consultation with the Council, NMFS is implementing measures for the recreational haddock fishery to ensure that recreational catches of GOM haddock and cod do not exceed the recreational sub-annual catch limits (sub-ACLs) for these stocks. This rule implements a 17-inch (43.2-cm) minimum size for haddock, which is a decrease from the 21-inch (53.3-cm) minimum fish size for haddock in effect for fishing year 2014. The possession limit for GOM haddock will remain three fish per angler, and the seasonal possession restrictions for haddock will be unchanged (September 1, 2015, through October 31, 2015; and March 1, 2016, through April 30, 2016). The recreational haddock measures implemented by this rule are dependent on the fishing year 2015 recreational sub-ACLs, and a zero-possession limit for GOM cod, being implemented by Framework 53. Despite prohibiting recreational possession of GOM cod, the GOM haddock measures have a direct impact on achieving or exceeding the GOM cod sub-ACL because of cod bycatch in the haddock fishery (cod discard mortality counts against the cod sub-ACL).

These measures are expected to result in fishing year 2015 recreational GOM cod and haddock catches lower than the sub-ACLs of 121 mt for cod and 372 mt for haddock, as explained further below. The fishing year 2015 recreational measures for GOM cod and haddock are specified in Table 1 with information on fishing year 2014 measures for comparison.

TABLE 1—GOM COD AND HADDOCK RECREATIONAL MANAGEMENT MEASURES FOR FISHING YEAR 2015 AND CHANGES FROM FISHING YEAR 2014 MEASURES

| Species | 2015 Measures | | | 2014 Measures | | |
|---|---|---|---|---|---|---|
| | Per day possession limit (fish per angler) | Minimum fish size | Possession prohibited (GOM area) | Per day possession limit | Minimum fish size | Possession prohibited (GOM area) |
| Cod* | 0 | Not Applicable | May 1, 2015–April 30, 2016. | 9 | 21 inches (53.3 cm) | September 1, 2014–April 14, 2015. |
| Haddock | 3 | 17 inches (43.2 cm) | September 1–October 31, 2015 and March 1–April 30, 2016. | 3 | 21 inches (53.3 cm) | September 1–October 31, 2014 and March 1–April 30, 2015. |

* The recreational cod measures are set in the final rule implementing Framework Adjustment 53.

We are also implementing four additional measures to facilitate the implementation and enforcement of the recreational possession limit for GOM haddock, which differs from the recreational possession limit for Georges Bank haddock, under our authority specified in section 305(d) of the Magnuson-Stevens Act. First, for purposes of counting fish, fillets will be converted to whole fish by dividing the number of fillets by two. However, if fish are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole fish. Second, haddock harvested by recreational fishing vessels with more than one person aboard may be pooled in one or more containers. Compliance with the possession limit will be determined by dividing the number of fish on board by the number of people on board. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner or operator of the vessel. Third, haddock must be stored so as to be readily available for inspection. Fourth, the regulations specifying how to calculate the possession limit for multi-day trips will be revised to apply to haddock as well as cod.

## Background

The GOM cod and haddock recreational catch estimates indicate that the estimated fishing year 2014 GOM cod catch is 561 mt and 505 mt for GOM haddock. These catch estimates significantly exceed the fishing year 2014 sub-ACLs, which are 486 mt for GOM cod and 173 mt for GOM haddock. For fishing year 2015, the Council has recommended a recreational sub-ACL of 121 mt for GOM cod and a recreational sub-ACL of 372 mt for GOM haddock. These catch limits were previously published in a proposed rule with the Council's catch recommendations, and other fishing year 2015 management measures contained in Framework 53 to the FMP for May 1, 2015, implementation. The proposed and final rules for Framework 53 (when published), along with supporting analyses for Framework 53, can be found at the Federal electronic rulemaking portal: Regulations.gov. Reference docket NOAA–NMFS–2015–0020. *http://www.regulations.gov/#!documentDetail;D=NOAA-NMFS-2015-0020-0001.*

As specified in Table 2, in order to not exceed the recommended sub-ACLs in fishing year 2015, recreational catch must be reduced from actual 2014 catch estimates by 78 percent for GOM cod and 84 percent for GOM haddock. The

supplemental EA containing the analyses for this action is available as outlined in the **ADDRESSESS** section of this rule's preamble.

TABLE 2—PRELIMINARY FISHING YEAR 2014 AND 2015 RECREATIONAL CATCH INFORMATION FOR GOM COD AND HADDOCK

[All weights in mt]

| GOM stock | 2014 sub-ACL | Total catch | % of 2014 sub-ACL caught | 2015 sub-ACL | Reduction in landings needed for 2015 (percent) |
|---|---|---|---|---|---|
| Cod | 486 | 561 | 115 | 121 | 78 |
| Haddock | 173 | 505 | 292 | 372 | 84 |

**Council Recommendations**

As part of the accountability measure consultation process, the Council convened its Recreational Advisory Panel (RAP) on January 22, 2015, to recommend management measure changes for the Council's consideration. The RAP reviewed catch projections under various scenarios of changed measures for fishing year 2015 modeled by the Northeast Fisheries Science Center's Social Sciences Branch (SSB). SSB staff used a model that was peer-reviewed in 2012 by the Council's Scientific and Statistical Committee. This bioeconomic simulation model predicts the expected number of GOM cod and haddock that would be kept and discarded from alternative seasons, and possession and size limits. Despite prohibiting recreational possession of GOM cod, the GOM haddock measures have a direct impact on achieving or exceeding the GOM cod sub-ACL because of cod bycatch in the haddock fishery.

The RAP's recommendations were discussed by the Council at its January 29, 2015, meeting. The RAP and Council recommended that the minimum size for GOM haddock be reduced from 21 inches (53.3 cm) to 17 inches (43.2 cm), that the possession limit for GOM haddock increase from 3 fish to 4 fish, and the seasonal possession restriction for haddock remain unchanged (September 1, 2015, through October 31, 2015, and March 1, 2016, through April 30, 2016). Reducing the minimum size would reduce discards because there are a large number of haddock in the 17-inch (43.2-cm) to 20-inch (50.8-cm) range, which would result in anglers achieving their bag limit more quickly under the smaller minimum size. However, the bio-economic model predicted that these measures are unlikely to keep haddock catch and the resulting cod bycatch from exceeding the fishing year 2015 recreational catch limits. Based on the model estimates, these recommended measures could result in catches below the recreational sub-ACLs only if discard mortality for cod and haddock were reduced, while compliance was increased. To address this, the Council and RAP recommended gear requirements to reduce recreational discard mortality, and outreach to increase compliance with the recreational measures.

Specifically, the Council and RAP recommended prohibiting the use of more than two hooks per line while fishing for groundfish in the GOM, requiring that in-line circle hooks be used with bait, and requiring that jigs and artificial lures use only single point J-hooks (*e.g.,* no treble hooks). NMFS considered these gear measures, but is not implementing them because of a lack of available conclusive scientific evidence that the recommended gear restrictions would have positive conservation benefits in the GOM recreational groundfish fishery. However, NMFS is continuing its increased outreach efforts and expects that this will result in increased compliance with the cod and haddock recreational measures in fishing year 2015.

More substantial background on this action, including details on the measures recommended by the RAP and the Council, and the resulting projected catch in fishing year 2015 associated with those options, can be found in the supplemental EA prepared for this action. Additional information regarding the presentations and discussions held by the RAP and Council are available on the Council's Web site: *http://www.nefmc.org/.*

**Model Assumptions Used in Analysis**

The estimated recreational catches for GOM cod and haddock come from the bio-economic model developed by the SSB. The model estimates that fishing year 2015 effort will decline a further 12 to 15 percent from fishing year 2014, based on preliminary estimates. However, the bio-economic model is limited in its ability to account for how a zero possession limit for GOM cod will affect effort because there are no available historical data for cod catch during a period when cod possession was prohibited while haddock retention was permitted. During September and October of 2014, recreational possession of both cod and haddock was prohibited. During that time (MRIP Wave 5), recreational angler trips declined 85 percent compared to the same period in 2013. The 85-percent decline in angler trips is an indication that prohibiting recreational possession of cod will likely cause a substantial reduction in effort, beyond what the model is estimating, but the reduction is expected to be less than 85 percent because anglers would be able to retain three haddock per trip.

In analyzing this action, we have adopted a new lower estimate of recreational cod discard mortality than what was used in the most recent stock assessment. At the time of the assessment, there were no directed field studies available to better inform the estimate. However, a recently conducted study provides preliminary GOM cod recreational discard mortality estimates. After reviewing the study, Northeast Fisheries Science Center staff determined that the 15-percent estimate derived from this study has a stronger scientific justification than the 30-percent rate previously used in the assessment.

For fishing year 2015 catch estimates, the model also incorporates non-compliance estimates from the MRIP survey to improve the model's ability to accurately predict catches. The non-compliance estimates from MRIP represent unintentional non-compliance, which we are addressing with a new outreach and education plan for recreational fisheries.

**Analysis of Measures for Fishing Year 2015**

The model predicts that the measures implemented by this action have greater than a 50-percent probability of keeping mortality of GOM haddock below the

fishing year 2015 sub-ACL, but less than a 50-percent probability of limiting mortality of GOM cod to the sub-ACL (Table 3). However, as discussed above, we have concluded that the model likely overestimates cod catch (because the model does not consider potential changes in fishing behavior that may result from the zero cod possession limit) and we expect a reduction of at least 10 percent below the model estimate, such that cod catch would be below the recreational sub-ACL due to decreased effort targeting cod. Therefore, we expect that there is at least a 50-percent probability that recreational GOM cod and haddock catch will stay within their respective sub-ACLs under these measures.

TABLE 3—PROJECTED FISHING YEAR 2015 RECREATIONAL COD AND HADDOCK MORTALITY IN COMPARISON TO SUB-ACLS

| Cod mortality | | Haddock mortality | |
|---|---|---|---|
| Metric tons | Percent of sub-ACL | Metric tons | Percent of sub-ACL |
| 132 | 109 | 323 | 87 |

The model also predicts that the reduction in minimum size would result in a slight increase in the number of angler trips in the recreational fishery for GOM haddock. Because the minimum size for haddock is being reduced, a reduction in catch of cod and haddock is expected despite forecasting a slight increase in trips when compared to maintaining the current recreational minimum size of 21 inches (53.3 cm). There are a large number of haddock in the 17-inch (43.2-cm) to 20-inch (50.8-cm) range, which will result in anglers achieving their bag limit more quickly and discarding fewer fish than under the 21-inch (53.3-cm) minimum size. There is little high-grading in the recreational groundfish fishery and anglers are expected to end their trip or target other species after reaching their haddock bag limit.

**2. Regulatory Corrections Under Regional Administrator Authority**

In § 648.89(b)(1), an unnecessary acronym is removed and the default minimum size for cod caught inside the GOM Regulated Mesh Area is added to the minimum fish size table. Previously, this default minimum size was specified in a separate paragraph, so this change is intended to improve readability for the public. These changes were previously proposed along with measures to implement Framework Adjustment 53 (80 FR 12394). No comments were received on these changes. These changes are made as part of this rule to ensure the updates to § 648.89(b)(1) necessary to implement the reduced minimum size for haddock in this action do not overwrite the needed changes.

**Classification**

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has made a determination that this interim final rule is consistent with the Northeast Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

Pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Assistant Administrator for Fisheries finds good cause to waive the otherwise applicable requirements for both notice and comment rulemaking and a 30-day delay in effectiveness for this interim final action implementing fishing year 2015 recreational GOM haddock management measures. As explained in further detail below, the availability of information necessary to ensure that measures were in place for the May 1, 2015, start of the fishing year made it impracticable to provide prior notice and comment without sacrificing needed conservation benefits.

Because of the need to consider data and consult with the Council on this action, it was not possible to provide opportunity for prior notice and comment before the start of the fishing year, May 1, 2015. The Council was unable to meet to discuss recreational measures and make recommendations to NMFS until January 29, 2015. If these measures are not in place by the start of the fishing year, important conservation benefits may be lost. The majority of the recreational fishery occurs in the late spring and early summer months. Over the last three years (fishing years 2012–2014), an average of 28 percent of the recreational fishery has occurred in May and June (Wave 3). Delaying implementation of fishing year 2015 measures until sometime after May 1, 2015, would allow the recreational fishery for haddock to occur without the new measures during some or all of one of the busiest recreational seasons of the year. Even if the foregone benefits could be made up it would require the implementation of even more stringent measures with possibly more negative social and economic impacts to fishery participants to ensure total catch limits for the year are not exceeded. Doing so undermines the purpose of the rule and would be contrary to the public interest. Development of measures was publicly discussed at a RAP meeting and a Council meeting in January 2015, and NMFS is soliciting public comment on the interim measures contained in this rule.

For these same reasons, NMFS finds it necessary to waive the delayed effective date for this action. By implementing these measures through an interim final rule, NMFS will receive comments on this rule. These comments will be considered and any necessary changes to these measures can be made at a later date via appropriate rulemaking procedures.

This interim final rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866.

This interim final rule does not contain policies with Federalism or ''takings'' implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

This interim final rule is exempt from the procedures of the Regulatory Flexibility Act and the requirement to prepare a final regulatory flexibility analysis as required by 5 U.S.C. 604 because the rule is issued without opportunity for prior notice and opportunity for public comment.

**List of Subjects in 50 CFR Part 648**

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: April 20, 2015

**Eileen Sobeck,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

## PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.89:

■ a. Revise paragraphs (b) and (c)(4).

■ b. Lift the suspension of paragraph (c)(8) published December 29, 2014 (79 FR 77953).

■ c. Remove paragraph (c)(8) published November 13, 2014 (79 FR 67375) and effectiveness extended December 29, 2014 (79 FR 77946).

■ d. Add a new paragraph (c)(8).

The revisions and addition read as follows:

**§ 648.89 Recreational and charter/party vessel restrictions.**

* * * * *

(b) *Recreational minimum fish sizes*—(1) *Minimum fish sizes.* Unless further restricted under this section, persons aboard charter or party boats permitted under this part and not fishing under the NE multispecies DAS program or under the restrictions and conditions of an approved sector operations plan, and private recreational fishing vessels in or possessing fish from the EEZ, may not possess fish smaller than the minimum fish sizes, measured in total length, as follows:

| Species | Minimum size | |
|---|---|---|
| | Inches | cm |
| Cod: | | |
| Inside GOM Regulated Mesh Area [1] | 21 | 53.3 |
| Outside GOM Regulated Mesh Area [1] | 22 | 55.9 |
| Haddock: | | |
| Inside GOM Regulated Mesh Area | 17 | 43.2 |
| Outside GOM Regulated Mesh Area | 18 | 45.7 |
| Pollock | 19 | 48.3 |
| Witch Flounder (gray sole) | 14 | 35.6 |
| Yellowtail Flounder | 13 | 33.0 |
| American Plaice (dab) | 14 | 35.6 |
| Atlantic Halibut | 41 | 104.1 |
| Winter Flounder (blackback) | 12 | 30.5 |
| Redfish | 9 | 22.9 |

[1] GOM Regulated Mesh Area specified in § 648.80(a).

(2) *Exception.* Vessels may possess fillets less than the minimum size specified, if the fillets are taken from legal-sized fish and are not offered or intended for sale, trade or barter.

(3) Fish fillets, or parts of fish, must have at least 2 square inches (5.1 square cm) of skin on while possessed on board a vessel and at the time of landing in order to meet minimum size requirements. The skin must be contiguous and must allow ready identification of the fish species.

(c) * * *

(4) *Accounting of daily trip limit.* For the purposes of determining the per day trip limit for cod and haddock for private recreational fishing vessels and charter or party boats, any trip in excess of 15 hours and covering 2 consecutive calendar days will be considered more than 1 day. Similarly, any trip in excess of 39 hours and covering 3 consecutive calendar days will be considered more than 2 days and, so on, in a similar fashion.

* * * * *

(8) *Haddock.* (i) Each person on a charter or party boat permitted under this part, or on a private recreational fishing vessel fishing in the EEZ, may possess no more than three haddock per day in, or harvested from, the EEZ when fishing inside of the GOM Regulated Mesh Area specified in § 648.80(a)(1); with the exception that private recreational vessels and charter or party boats in possession of haddock caught outside the GOM Regulated Mesh Area may transit this area, provided all bait and hooks are removed from fishing rods and any haddock on board has been gutted and stored.

(ii) Each person on a charter or party boat permitted under this part, or on a private recreational fishing vessel fishing in the EEZ, may possess unlimited haddock in, or harvested from, the EEZ when fishing outside of the GOM Regulated Mesh Area specified in § 648.80(a)(1).

(iii) For purposes of counting fish, fillets will be converted to whole fish at the place of landing by dividing the number of fillets by two. If fish are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole fish.

(iv) Haddock harvested in or from the EEZ by private recreational fishing boats or charter or party boats with more than one person aboard may be pooled in one or more containers. Compliance with the possession limit will be determined by dividing the number of fish on board by the number of persons on board. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner or operator of the vessel.

(v) Haddock must be stored so as to be readily available for inspection.

* * * * *

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Part V

## Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310

Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 310**

**[Docket No. FDA–2015–N–0101] (Formerly Docket No. FDA–1975–N–0012)**

**RIN 0910–AF69**

# Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this proposed rule to amend the 1994 tentative final monograph or proposed rule (the 1994 TFM) for over-the-counter (OTC) antiseptic drug products. In this proposed rule, we are proposing to establish conditions under which OTC antiseptic products intended for use by health care professionals in a hospital setting or other health care situations outside the hospital are generally recognized as safe and effective. In the 1994 TFM, certain antiseptic active ingredients were proposed as being generally recognized as safe for use in health care settings based on safety data evaluated by FDA as part of its ongoing review of OTC antiseptic drug products. However, in light of more recent scientific developments, we are now proposing that additional safety data are necessary to support the safety of antiseptic active ingredients for these uses. We also are proposing that all health care antiseptic active ingredients have in vitro data characterizing the ingredient's antimicrobial properties and in vivo clinical simulation studies showing that specified log reductions in the amount of certain bacteria are achieved using the ingredient.

**DATES:** Submit electronic or written comments by October 28, 2015. See section VIII of this document for the proposed effective date of a final rule based on this proposed rule.

**ADDRESSES:** You may submit comments by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

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

**Written Submissions**

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Docket No. FDA–2015–N–0101 (formerly Docket No. FDA–1975–N–0012) and RIN 0910–AF69 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Earlier FDA publications, public submissions, and other materials relevant to this rulemaking may also be found under Docket No. FDA–1975–N–0012 (formerly Docket No. 1975N–0183H) using the same procedures.

**FOR FURTHER INFORMATION CONTACT:** Michelle M. Jackson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5411, Silver Spring, MD 20993, 301–796–2090.

**SUPPLEMENTARY INFORMATION:**

## Executive Summary

### *Purpose of the Regulatory Action*

FDA is proposing to amend the 1994 TFM for OTC antiseptic drug products that published in the **Federal Register** of June 17, 1994 (59 FR 31402). The 1994 TFM is part of FDA's ongoing rulemaking to evaluate the safety and effectiveness of OTC drug products marketed in the United States on or before May 1972 (OTC Drug Review).

FDA is proposing to establish new conditions under which OTC health care antiseptic active ingredients are generally recognized as safe and effective (GRAS/GRAE) based on FDA's reevaluation of the safety and effectiveness data requirements proposed in the 1994 TFM in light of comments received, input from subsequent public meetings, and our independent evaluation of other relevant scientific information we have identified and placed in the administrative file. These health care antiseptic products include health care personnel hand washes, health care personnel hand rubs, surgical hand scrubs, surgical hand rubs, and patient preoperative skin preparations.

### *Summary of the Major Provisions of the Regulatory Action in Question*

We are proposing that additional safety and effectiveness data are necessary to support a GRAS/GRAE determination for OTC antiseptic active ingredients intended for use by health care professionals. The effectiveness data, the safety data, and the effect on the previously proposed classification of active ingredients are described briefly in this summary.

#### *Effectiveness*

A determination that a drug product containing a particular active ingredient would be generally recognized as effective (GRAE) for a particular intended use requires consideration of the benefit-to-risk ratio for the drug for that use. New information on potential risks posed by the use of certain health care antiseptic products, as well as input from the Nonprescription Drugs Advisory Committee (NDAC) that met in March 2005 (the March 2005 NDAC), has prompted us to reevaluate the data needed for classifying health care antiseptic active ingredients as GRAE (see new information described in the Safety section of this summary). We continue to propose the use of surrogate endpoints (bacterial log reductions) as a demonstration of effectiveness for health care antiseptics combined with in vitro testing to characterize the antimicrobial activity of the ingredient. However, the log reductions required for the demonstration of effectiveness for health care antiseptics have been revised based on the recommendations of the March 2005 NDAC, comments received after the 1994 TFM, and other information that FDA reviewed.

We have evaluated the available literature and the data and other information that were submitted to the rulemaking on the effectiveness of health care antiseptic active ingredients, as well as the recommendations from the public meetings held by the Agency on antiseptics. We propose that the record should contain additional log reduction data to demonstrate the effectiveness of health care antiseptic active ingredients.

#### *Safety*

Several important scientific developments that affect the safety evaluation of these ingredients have occurred since FDA's 1994 evaluation of the safety of health care antiseptic active ingredients under the OTC Drug

Review. Improved analytical methods now exist that can detect and more accurately measure these active ingredients at lower levels in the bloodstream and tissue. Consequently, we now know that, at least for certain health care antiseptic ingredients, systemic exposure is higher than previously thought (Refs. 1 through 5), and new information is available about the potential risks from systemic absorption and long-term exposure. New safety information also suggests that widespread antiseptic use could have an impact on the development of bacterial resistance. Currently, the significance of this new information is not known and we are unaware of any information that would lead us to conclude that any health care antiseptic active ingredient is unsafe (other than those that we proposed to be Category II in the 1994 TFM). The benefits of any active ingredient will need to be weighed against its risks once both the effectiveness and safety have been better characterized to determine GRAS/GRAE status.

The previously proposed generally recognized as safe (GRAS) determinations were based on safety principles that have since evolved significantly because of advances in technology, development of new test methods, and experience with performing test methods. The standard battery of tests that were used to determine the safety of drugs has changed over time to incorporate improvements in safety testing. To ensure that health care antiseptic active ingredients are GRAS, data that meet current safety standards are needed.

Based on these developments, we are now proposing that additional safety data are needed for each health care antiseptic active ingredient to support a GRAS classification. The data described in this proposed rule are the minimum data necessary to establish the safety of antiseptic active ingredients used in health care antiseptic products in light of the new safety information. Health care practitioners may use health care antiseptics on a daily, long-term (*i.e.,* chronic) basis. Patient preoperative skin preparations, on the other hand, are not usually used on any single patient on a daily basis. Nevertheless, an individual may be exposed to patient preoperative skin preparations (particularly those used for preinjection skin preparation) enough times over a lifetime to be considered a chronic use. The data we propose are needed to demonstrate safety for all health care antiseptic active ingredients fall into four broad categories: (1) Human safety studies described in current FDA guidance (*e.g.,* maximal use trials or MUsT), (2) nonclinical safety studies described in current FDA guidance (*e.g.,* developmental and reproductive toxicity studies and carcinogenicity studies), (3) data to characterize potential hormonal effects, and (4) data to evaluate the development of antimicrobial resistance.

We emphasize that our proposal for more safety and effectiveness data for health care antiseptic active ingredients does not mean that we believe that health care antiseptic products containing these ingredients are ineffective or unsafe, or that their use should be discontinued. However, now that we have enhanced abilities to measure and evaluate the safety and effectiveness of these ingredients, we believe we should obtain relevant data to support a GRAS/GRAE determination. Consequently, based on new information and improvements in safety testing and in our understanding of log reduction testing and the use of surrogate endpoints since our 1994 evaluation, we are requesting more safety and effectiveness data to ensure that these health care antiseptic active ingredients meet the updated standards to support a GRAS/GRAE classification. Considering the prevalent use of health care antiseptic products in health care settings, it is critical that the safety and effectiveness of these ingredients be supported by data that meet the most current standards.

*Active Ingredients*

In the 1994 TFM, 27 antiseptic active ingredients were classified for three OTC health care antiseptic uses: (1) Patient preoperative skin preparation, (2) health care personnel hand wash, and (3) surgical hand scrub (59 FR 31402 at 31435) (for a list of all active ingredients covered by this proposed rule, see tables 4 through 7). Our detailed evaluation of the effectiveness and safety of the active ingredients for which data were submitted can be found in sections VI.A and VII.D. In the 1994 TFM, alcohol (60 to 95 percent) and povidone-iodine (5 to 10 percent), which are active ingredients that are being evaluated for use as a health care antiseptic in this proposed rule, were proposed to be classified as GRAS/GRAE (59 FR 31402 at 31435–31436) for patient preoperative skin preparation, health care personnel hand wash, and surgical hand scrub. Iodine tincture, iodine topical solution, and isopropyl alcohol were proposed to be classified as GRAS/GRAE for patient preoperative skin preparations (59 FR 31402 at 31435–31436). However, we now propose that the health care antiseptic active ingredients classified as GRAS/GRAE for use in health care antiseptics in the 1994 TFM need additional safety and effectiveness data to support a classification of GRAS/GRAE for health care antiseptic use.

Several health care antiseptic active ingredients evaluated in the 1994 TFM were proposed as GRAS, but not GRAE, for use in health care antiseptics because they lacked sufficient evidence of effectiveness for health care use (see tables 4 and 5). We are now proposing that these ingredients need additional safety data, as well as effectiveness data, to be classified as GRAS/GRAE.

The data available and the data that are missing are discussed separately for each active ingredient in this proposed rule. For those ingredients for which no data have been submitted since the 1994 TFM, we have not included a separate discussion section, but have indicated in table 10 that no additional data were submitted or identified.

In certain cases, manufacturers may have the data we propose as necessary in this proposed rule, but to date these data have not been submitted to the OTC Drug Review. Although currently we expect to receive the necessary data, if we do not obtain sufficient data to support monograph conditions for health care antiseptic products containing these active ingredients, these products may not be included in the future OTC health care antiseptic final monograph. Any health care antiseptic product containing the active ingredients being considered under this rulemaking that are not included in a future final monograph could obtain approval to market by submitting new drug applications (NDAs) under section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355). After a final monograph is established, these products might be able to submit NDA deviations in accordance with § 330.11 (21 CFR 330.11), limiting the scope of review necessary to obtain approval.

*Costs and Benefits*

Benefits represent the monetary values associated with reducing the potential adverse health effects associated with the use of health care antiseptic products containing active ingredients that could potentially be shown to be unsafe or ineffective for their intended use. We estimate annual benefits to roughly range between $0 and $0.16 million. Total upfront costs are estimated to range between $64 and $90.8 million. Annualizing these costs over a 10-year period, we estimate total annualized costs to range from $7.3 and $10.4 million at a 3 percent discount

rate to $8.5 and $12.1 million at a 7 percent discount rate. Potential one-time costs include the expenditures to conduct various safety and effectiveness tests, and to reformulate and relabel products that contain nonmonograph ingredients.

| Summary of costs and benefits of the proposed rule | Total benefits annualized over 10 years (in millions) | Total costs annualized over 10 years (in millions) | Total one-time costs (in millions) |
|---|---|---|---|
| Total | $0.0 to $0.16 | $7.3 to $10.4 at (3%)<br>$8.5 to $12.1 at (7%) | $64.0 to $90.8 |

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## I. Introduction

In the following sections, we provide a brief description of terminology used in the OTC Drug Review regulations and an overview of OTC topical antiseptic drug products, and then describe in more detail the OTC health care antiseptics that are the subject of this proposed rule.

### *A. Terminology Used in the OTC Drug Review Regulations*

#### 1. Proposed, Tentative Final, and Final Monographs

To conform to terminology used in the OTC Drug Review regulations (§ 330.10), the September 1974 advance notice of proposed rulemaking (ANPR) was designated as a ''proposed monograph.'' Similarly, the notices of proposed rulemaking, which were published in the **Federal Register** of January 6, 1978 (43 FR 1210) (the 1978 TFM), and in the **Federal Register** of June 17, 1994 (59 FR 31402) (the 1994 TFM), were each designated as a ''tentative final monograph.'' The present proposed rule, which is a reproposal regarding health care antiseptic drug products, is also designated as a ''tentative final monograph.''

#### 2. Category I, II, and III Classifications

The OTC drug procedural regulations in § 330.10 use the terms ''Category I'' (generally recognized as safe and effective and not misbranded), ''Category II'' (not generally recognized as safe and effective or misbranded), and ''Category III'' (available data are insufficient to classify as safe and effective, and further testing is required). Section 330.10 provides that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph (*i.e.,* a final rule or regulation). Therefore, this proposed rule (at the tentative final monograph stage) retains the concepts of Categories I, II, and III.

At the final monograph stage, FDA does not use the terms ''Category I,'' ''Category II,'' and ''Category III.'' In place of Category I, the term ''monograph conditions'' is used; in place of Categories II and III, the term ''nonmonograph conditions'' is used.

### *B. Topical Antiseptics*

The OTC topical antimicrobial rulemaking has had a broad scope, encompassing drug products that may contain the same active ingredients, but that are labeled and marketed for different intended uses. In 1974, the Agency published an ANPR for topical antimicrobial products that encompassed products for both health care and consumer use (39 FR 33103, September 13, 1974). The ANPR covered seven different intended uses for these products: (1) Antimicrobial soap, (2) health care personnel hand wash, (3) patient preoperative skin preparation, (4) skin antiseptic, (5) skin wound cleanser, (6) skin wound protectant, and (7) surgical hand scrub (39 FR 33103 at 33140). FDA subsequently identified skin antiseptics, skin wound cleansers, and skin wound protectants as antiseptics used primarily by consumers for first aid use and referred to them collectively as ''first aid antiseptics.'' We published a separate TFM covering the first aid antiseptics in the **Federal Register** of July 22, 1991 (56 FR 33644) (1991 First Aid TFM). Thus, first aid antiseptics are not discussed further in this document.

The four remaining categories of topical antimicrobials were addressed in the 1994 TFM. The 1994 TFM covered: (1) Antiseptic hand wash (*i.e.,* consumer hand wash), (2) health care personnel hand wash, (3) patient preoperative skin preparation, and (4) surgical hand scrub (59 FR 31402 at 31442). In the 1994 TFM, FDA also identified a new category of antiseptics for use by the food industry and requested relevant data and information (59 FR 31402 at 31440). Antiseptics for use by the food industry are not discussed further in this document.

As we proposed in the consumer antiseptic wash proposed rule published in the **Federal Register** of December 17, 2013 (78 FR 76444) (the Consumer Wash PR), our evaluation of OTC antiseptic drug products is being further subdivided into health care antiseptics and consumer antiseptics. We believe that these categories are distinct based on the proposed use setting, target population, and the fact

that each setting presents a different level of risk for infection. For example, in health care settings, the patient population is generally more susceptible to infection than the general U.S. consumer population (*i.e.,* the population who use consumer antiseptic washes). Consequently, in the health care setting, the potential for spread of infection and the potential for serious outcomes of infection may be relatively higher than in the U.S. consumer setting. Therefore, the safety and effectiveness should be evaluated separately for each intended use to support a GRAS/GRAE determination.

Health care antiseptics are drug products intended for use by health care professionals in a hospital setting or other health care situations outside the hospital. Patient preoperative skin preparations, which include products that are used for preparation of the skin prior to an injection (*i.e.,* preinjection), may be used by patients outside the traditional health care setting. Some patients (*e.g.,* diabetics who manage their disease with insulin injections) self-inject medications that have been prescribed by a health care professional at home or at other locations and use patient preoperative skin preparations prior to injection. In 1974, when the ANPR (39 FR 33103) to establish an OTC topical antimicrobial monograph was published in the **Federal Register,** antimicrobial soaps used by consumers were distinct from professional use antiseptics, such as health care personnel hand washes. (See 78 FR 76444 for further discussion of the term ''antimicrobial soaps.'') In contrast, in the 1994 TFM, we proposed that both consumer antiseptic hand washes and health care personnel hand washes should have the same effectiveness testing and performance criteria. In response to the 1994 TFM, we received submissions from the public arguing that consumer products serve a different purpose and should continue to be distinct from health care antiseptics. We agree, and in this proposed rule, we make a distinction between consumer antiseptics for use by the general population and health care antiseptics for use in hospitals or in other specific health care situations outside the hospital.

The health care setting is different from the consumer setting in many ways. Among other things, health care facilities employ frequent, standardized disinfection procedures and stringent infection control measures that include the use of health care antiseptics. The use of these measures is critical to preventing the spread of infection within health care facilities. The population in a hospital or health care facility also is different from the general consumer population. In addition, the microorganisms of concern are different in the health care and consumer settings. These differences have resulted in our proposing different effectiveness data requirements. (See section VI.B. about the different effectiveness data requirements.)

*C. This Proposed Rule Covers Only Health Care Antiseptics*

We refer to the group of products covered by this proposed rule as ''health care antiseptics.'' In this proposed rule, FDA proposes the establishment of a monograph for OTC health care antiseptics that are intended for use by health care professionals in a hospital setting or other health care situations outside the hospital, but that are not identified as ''first aid antiseptics'' in the 1991 First Aid TFM. In this proposed rule, we use the term ''health care antiseptics'' to include the following products:

- Health care personnel hand washes
- health care personnel hand rubs
- surgical hand scrubs
- surgical hand rubs
- patient preoperative skin preparations

This proposed rule covers products that are rubs and others that are washes. The 1994 TFM did not distinguish between products that we are now calling ''antiseptic washes'' and products we are now calling ''antiseptic rubs.'' Washes are rinsed off with water, and include health care personnel hand washes and surgical hand scrubs. Rubs are sometimes referred to as ''leave-on products'' and are not rinsed off after use. Rubs include health care personnel hand rubs, surgical hand rubs, and patient preoperative skin preparations.

The 1994 TFM did not distinguish between consumer antiseptic washes and rubs, and health care hand washes and rubs. This proposed rule covers health care personnel hand washes and health care personnel hand rubs, as well as the other health care antiseptic categories previously listed in this section. This proposed rule does not cover consumer antiseptic washes or consumer antiseptic hand rubs.

Completion of the monograph for Health Care Antiseptic Products and certain other monographs for the active ingredient triclosan are subject to a Consent Decree entered by the United States District Court for the Southern District of New York on November 21, 2013, in *Natural Resources Defense Council, Inc.* v. *United States Food and Drug Administration, et al.,* 10 Civ. 5690 (S.D.N.Y.).

*D. Comment Period*

Because of the complexity of this proposed rule, we are providing a comment period of 180 days. Moreover, new data or information may be submitted to the docket via *http://www.regulations.gov* within 12 months of publication, and comments on any new data or information may then be submitted for an additional 60 days (see § 330.10(a)(7)(iii) and (a)(7)(iv)). In addition, FDA will also consider requests to defer further rulemaking with respect to a specific active ingredient to allow the submission of new safety or effectiveness data to the record if such requests are submitted to the docket within the initial 180-day comment period. Upon the close of the comment period, FDA will review all data and information submitted to the record in conjunction with all timely and complete requests to defer rulemaking. In assessing whether to defer further rulemaking for a particular active ingredient to allow for additional time for studies to generate new data and information, FDA will consider the data already in the docket along with any information that is provided in any requests. FDA will determine whether the sum of the data, if submitted in a timely fashion, is likely to be adequate to provide all the data that are necessary to make a determination of general recognition of safety and effectiveness.

We note that the OTC Drug Review is a public process and any data submitted is public. There is no requirement or expectation that more than one set of data will be submitted to the docket for a particular active ingredient, and it does not matter who submits the data. Additionally, data and other information for a single active ingredient may be submitted by any interested party and not all data for an ingredient must be submitted by a single party.

## II. Background

In this section, we describe the significant rulemakings and public meetings relevant to this proposed rule, and how we are responding to comments received in response to the 1994 TFM.

*A. Significant Rulemakings Relevant to This Proposed Rule*

A summary of the significant **Federal Register** publications relevant to this proposed rule is provided in table 1. Other **Federal Register** publications relevant to this proposed rule are available from the Division of Dockets Management (see **ADDRESSES**).

TABLE 1—SIGNIFICANT RULEMAKING PUBLICATIONS RELATED TO HEALTH CARE ANTISEPTIC DRUG PRODUCTS

| **Federal Register** notice | Information in notice |
|---|---|
| 1974 ANPR (September 13, 1974, 39 FR 33103). | We published an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial I Drug Products (Antimicrobial I Panel or Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. |
| 1978 Antimicrobial TFM (January 6, 1978, 43 FR 1210). | We published our tentative conclusions and proposed effectiveness testing for the drug product categories evaluated by the Panel. The 1978 TFM reflects our evaluation of the recommendations of the Panel and comments and data submitted in response to the Panel's recommendations. |
| 1982 Alcohol ANPR (May 21, 1982, 47 FR 22324). | We published an advance notice of proposed rulemaking to establish a monograph for alcohol drug products for topical antimicrobial use, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class (Miscellaneous External Panel). |
| 1991 First Aid TFM (July 22, 1991, 56 FR 33644). | We amended the 1978 TFM to establish a separate monograph for OTC first aid antiseptic products. In the 1991 First Aid TFM, we proposed that first aid antiseptic drug products be indicated for the prevention of skin infections in minor cuts, scrapes, and burns. |
| 1994 Health-Care Antiseptic TFM (June 17, 1994, 59 FR 31402). | We amended the 1978 TFM to establish a separate monograph for the group of products that were referred to as OTC topical health care antiseptic drug products. These antiseptics are generally intended for use by health care professionals.<br>In that proposed rule, we also recognized the need for antibacterial personal cleansing products for consumers to help prevent cross contamination from one person to another and proposed a new antiseptic category for consumer use: Antiseptic hand wash. |
| 2013 Consumer Antiseptic Wash TFM (December 17, 2013, 78 FR 76444). | We issued a proposed rule to amend the 1994 TFM and to establish data standards for determining whether OTC consumer antiseptic washes are GRAS/GRAE.<br>In that proposed rule, we proposed that additional safety and effectiveness data are necessary to support the safety and effectiveness of consumer antiseptic wash active ingredients. |

*B. Public Meetings Relevant to This Proposed Rule*

In addition to the **Federal Register** publications listed in table 1, there have been three meetings of the NDAC and one public feedback meeting that are relevant to the discussion of health care antiseptic safety and effectiveness. These meetings are summarized in table 2.

TABLE 2—PUBLIC MEETINGS RELEVANT TO HEALTH CARE ANTISEPTICS

| Date and type of meeting | Topic of discussion |
|---|---|
| January 1997 NDAC Meeting (Joint meeting with the Anti-Infective Drugs Advisory Committee) (January 6, 1997, 62 FR 764). | Antiseptic and antibiotic resistance in relation to an industry proposal for consumer and health care antiseptic effectiveness testing (Health Care Continuum Model) (Refs. 6 and 7). |
| March 2005 NDAC Meeting (February 18, 2005, 70 FR 8376). | The use of surrogate endpoints and study design issues for the in vivo testing of health care antiseptics (Ref. 8). |
| November 2008 Public Feedback Meeting ..... | Demonstration of the effectiveness of consumer antiseptics (Ref. 9). |
| September 2014 NDAC Meeting (July 29, 2014, 79 FR 44042). | Safety testing framework for health care antiseptic active ingredients (Ref. 10). |

*C. Comments Received by FDA*

In response to the 1994 TFM, FDA received approximately 160 comments from drug manufacturers, trade associations, academia, testing laboratories, consumers, health professionals, and law firms. Copies of the comments received are on public display at *http://www.regulations.gov* (see **ADDRESSES**).

Because only health care antiseptics are discussed in this proposed rule, only those comments and data received in response to the 1994 TFM that are related to health care antiseptic active ingredients are addressed. We also received comments related to final formulation testing and labeling conditions proposed in the 1994 TFM. If in the future we determine that there are monograph health care antiseptic active ingredients that are GRAS/GRAE, we will address these comments. We invite further comment on the final formulation testing and labeling conditions proposed in the 1994 TFM, particularly in light of the conditions proposed in this proposed rule. Comments that were received in response to the 1994 TFM regarding other intended uses of the active ingredients are addressed in the Consumer Antiseptic Wash TFM (78 FR 76444), or will be addressed in future documents related to those other uses.

This proposed rule constitutes FDA's evaluation of submissions made in response to the 1994 TFM to support the safety and effectiveness of OTC health care antiseptic active ingredients (Refs. 11 and 12). We reviewed the available literature and data and other comments submitted to the rulemaking and are proposing that adequate data for a determination of safety and effectiveness are not yet available for the health care antiseptic active ingredients.

## III. Active Ingredients With Insufficient Evidence of Eligibility for the OTC Drug Review

In this section of the proposed rule, we describe the requirements for

eligibility for the OTC Drug Review and the ingredients submitted to the OTC Drug Review that lack adequate evidence of eligibility for evaluation as health care antiseptic products.

*A. Eligibility for the OTC Drug Review*

An OTC drug is covered by the OTC Drug Review if its conditions of use existed in the OTC drug marketplace on or before May 11, 1972 (37 FR 9464).[1] Conditions of use include, among other things, active ingredient, dosage form and strength, route of administration, and specific OTC use or indication of the product (see § 330.14(a)). To determine eligibility for the OTC Drug Review, FDA typically must have actual product labeling or a facsimile of labeling that documents the conditions of marketing of a product prior to May 1972 (see § 330.10(a)(2)). FDA considers a drug that is ineligible for inclusion in the OTC monograph system to be a new drug that will require FDA approval through the NDA process. Ineligibility for use as a specific type of health care antiseptic (*e.g.,* health care personnel hand wash or surgical hand scrub) does not affect eligibility for other indications under the health care antiseptic monograph (*e.g.,* patient preoperative skin preparations) or under any other OTC drug monograph.

Section III.B discusses those ingredients that currently do not have adequate evidence of eligibility for evaluation under the OTC Drug Review based on a review of the labeling submitted to the Panel. Some ingredients are ineligible for any of the categories of health care antiseptics. Others are eligible for some, but not others. Because of their lack of eligibility, effectiveness and safety information that has been submitted to the rulemaking for these health care antiseptic active ingredients are not discussed in this proposed rule for such use(s). However, if documentation of the type described in this section is submitted, these active ingredients could be determined to be eligible for evaluation for such use(s).

*B. Eligibility of Certain Active Ingredients for Certain Health Care Antiseptic Uses Under the OTC Drug Review*

Table 3 lists the health care antiseptic active ingredients that have been considered under this rulemaking and shows whether each ingredient is eligible or ineligible for each of the five health care antiseptic uses: Patient preoperative skin preparation, health care personnel hand wash, health care personnel hand rub, surgical hand scrub, and surgical hand rub. After the table, we discuss the ineligibility of ingredients in this section of the proposed rule.

TABLE 3—ELIGIBILITY OF ANTISEPTIC ACTIVE INGREDIENTS FOR HEALTH CARE ANTISEPTIC USES [1]

| Active ingredient | Patient preoperative skin preparation | Health care personnel hand wash | Health care personnel hand rub | Surgical hand scrub | Surgical hand rub |
|---|---|---|---|---|---|
| Alcohol 60 to 95 percent | [2] Y | [3] N | Y | N | Y |
| Benzalkonium chloride | Y | Y | Y | Y | N |
| Benzethonium chloride | Y | Y | N | Y | N |
| Chlorhexidine gluconate | N | N | N | N | N |
| Chloroxylenol | Y | Y | N | Y | N |
| Cloflucarban | Y | Y | N | Y | N |
| Fluorosalan | Y | Y | N | Y | N |
| Hexylresorcinol | Y | Y | N | Y | N |
| Iodine Active Ingredients: | | | | | |
| Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate) | N | Y | N | Y | N |
| Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol) | Y | Y | N | Y | N |
| Iodine tincture USP | Y | N | N | N | N |
| Iodine topical solution USP | Y | N | N | N | N |
| Nonylphenoxypoly (ethyleneoxy) ethanoliodine | Y | Y | N | Y | N |
| Poloxamer-iodine complex | Y | Y | N | Y | N |
| Povidone-iodine 5 to 10 percent | Y | Y | N | Y | N |
| Undecoylium chloride iodine complex | Y | Y | N | Y | N |
| Isopropyl alcohol 70–91.3 percent | Y | N | Y | N | Y |
| Mercufenol chloride | Y | N | N | N | N |
| Methylbenzethonium chloride | Y | Y | N | Y | N |
| Phenol (less than 1.5 percent) | Y | Y | N | Y | N |
| Phenol (greater than 1.5 percent) | Y | Y | N | Y | N |
| Secondary amyltricresols | Y | Y | N | Y | N |
| Sodium oxychlorosene | Y | Y | N | Y | N |
| Triclocarban | Y | Y | N | Y | N |
| Triclosan | Y | Y | N | Y | N |
| Combinations: | | | | | |
| Calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative | Y | N | N | N | N |
| Mercufenol chloride and secondary amyltricresols in 50 percent alcohol | Y | N | N | N | N |
| Triple dye | Y | N | N | N | N |

[1] Hexachlorophene and tribromsalan are not included in this table because they are the subject of final regulatory action (see section IV).
[2] Y = Eligible for specified use.
[3] N = Ineligible for specified use.

[1] Also, note that drugs initially marketed in the United States after the OTC Drug Review began in 1972 and drugs without any U.S. marketing experience can be considered in the OTC monograph system based on submission of a time and extent application. (See § 330.14(c).)

1. Alcohols

a. *Alcohol (ethanol or ethyl alcohol).* In the 1994 TFM, alcohol (ethanol or ethyl alcohol) 60 to 95 percent by volume in an aqueous solution was evaluated for use as a health care personnel hand wash, surgical hand scrub, and patient preoperative skin preparation (59 FR 31402 at 31442). The only health care antiseptic products containing alcohol that were submitted to the OTC Drug Review were products that were intended to be used without water (*i.e.,* rubs and skin preparations) (Ref. 13). Consequently, based on the information we currently have about eligibility, we propose to categorize as new drugs these health care antiseptic washes and surgical scrubs (both of which are washes and are by definition intended to be rinsed off with water) that contain alcohol as the active ingredient, and we do not include a discussion of safety or effectiveness of alcohol for such rinse-off uses in this proposed rule.

Alcohol, however, has been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand rub, surgical hand rub, and patient preoperative skin preparation (59 FR 31402 at 31435–31436). Thus, we include a discussion of the safety and effectiveness data for alcohol in this proposed rule for such uses.

b. *Isopropyl alcohol.* In the 1994 TFM, isopropyl alcohol 70 to 91.3 percent by volume in an aqueous solution (isopropyl alcohol) was classified for use as a health care personnel hand wash and surgical hand scrub (59 FR 31402 at 31435–31436). Isopropyl alcohol also was evaluated as a patient preoperative skin preparation (59 FR 31402 at 31442–31443). The only health care antiseptic products containing isopropyl alcohol that were submitted to the OTC Drug Review were products that were intended to be used without water (*i.e.,* rubs and skin preparations) (Ref. 13). Consequently, isopropyl alcohol has not been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash or a surgical hand scrub drug product, both of which are washes and by definition are intended to be rinsed off with water. Thus, we propose to categorize isopropyl alcohol for these uses as a new drug and do not include a discussion of safety or effectiveness of isopropyl alcohol for such rinse-off uses in this proposed rule.

Isopropyl alcohol, however, has been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand rub, surgical hand rub, and patient preoperative skin preparation (59 FR 31402 at 31435–31436). Thus, we include a discussion of the safety and effectiveness data for isopropyl alcohol in this proposed rule for such uses.

2. Benzalkonium Chloride

Benzalkonium chloride has not been demonstrated to be eligible for the OTC Drug Review for use as a surgical hand rub. Based on the information we currently have about eligibility, we propose to categorize as a new drug benzalkonium chloride for use as a surgical hand rub. Benzalkonium chloride, however, has been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash, health care personnel hand rub, surgical hand scrub, and patient preoperative skin preparation (59 FR 31402 at 31435–31436). Thus, we include a discussion of the safety and effectiveness data for benzalkonium chloride in this proposed rule for such uses.

3. Chlorhexidine Gluconate

Previously, chlorhexidine gluconate 4 percent aqueous solution (chlorhexidine gluconate) was found to be ineligible for inclusion in the monograph for any health care antiseptic use and was not included in the 1994 TFM (59 FR 31402 at 31413). We have not received any new information since the 1994 TFM demonstrating that this active ingredient is eligible for the monograph. Consequently, we are not proposing to change the categorization of chlorhexidine gluconate from that of a new drug based on the lack of documentation demonstrating its eligibility as a health care antiseptic, and we do not include a discussion of any safety or effectiveness data submitted for chlorhexidine gluconate in this proposed rule.

4. Iodine and Iodine Complexes

a. *Iodine topical solution USP and iodine tincture USP.* Iodine topical solution and iodine tincture have not been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash or rub or as a surgical hand scrub or rub. Neither iodine topical solution nor iodine tincture was evaluated for these uses in the1994 TFM (59 FR 31402 at 31435–31436), and we have not received any new information to demonstrate eligibility for these uses since publication of the 1994 TFM. Based on the information we currently have about eligibility of iodine topical solution and iodine tincture, we propose to categorize as new drugs these iodines intended for use as a health care personnel hand wash or rub or as a surgical hand scrub or rub, and we do not include a discussion of safety or effectiveness of iodine solution or tincture for such uses in this proposed rule.

However, both iodine topical solution and iodine tincture have been demonstrated to be eligible for the OTC Drug Review for use as a patient preoperative skin preparation (59 FR 31402 at 31435–31436). Thus, we include a discussion of the safety and effectiveness of these iodines for this use in this proposed rule.

b. *Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate).* The only health care antiseptic products containing this iodine complex submitted to the OTC Drug Review were health care personnel hand washes and surgical hand scrubs intended to be used with water (Ref. 13). Consequently, iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate) has not been demonstrated to be eligible for the OTC Drug Review for evaluation as a health care personnel hand rub or a surgical hand rub, both of which are intended to be leave-on products used without water. This iodine complex also has not been demonstrated to be eligible for the OTC Drug Review for use as a patient preoperative skin preparation. It was not evaluated for use as a patient preoperative skin preparation in the 1994 TFM (59 FR 31402 at 31435–31436) and we have not received any new information to demonstrate eligibility for this use since publication of the 1994 TFM. Based on the information we currently have about eligibility of this active ingredient, we propose to categorize as a new drug iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate) intended for use as patient preoperative skin preparation as well. This iodine complex, however, has been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash and surgical hand scrub (59 FR 31402 at 31435–31436).

c. *Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol), nonylphenoxypoly (ethyleneoxy) ethanoliodine, poloxamer-iodine complex, and undecoylium chloride iodine complex.* The only health care antiseptic products containing these iodine complexes that were submitted to the OTC Drug Review were health care personnel hand washes and surgical hand scrubs intended to be used with water, and patient preoperative skin preparations (Ref. 13). Consequently, iodine complex

(phosphate ester of alkylaryloxy polyethylene glycol), nonylphenoxypoly (ethyleneoxy) ethanoliodine, poloxamer-iodine complex, and undecoylium chloride iodine complex have not been demonstrated to be eligible for the OTC Drug Review for evaluation as health care personnel hand rubs or surgical hand rubs (59 FR 31402 at 31418 and 31435–31436). Thus, we do not include a discussion of safety or effectiveness of these iodine complexes for these uses in this proposed rule.

These active ingredients, however, have been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash, a surgical hand scrub, and a patient preoperative skin preparation (59 FR 31402 at 31435–31436). Thus, we include a discussion of the safety and effectiveness of these ingredients for these uses in this proposed rule.

d. *Povidone-iodine 5 to 10 percent.* The only health care antiseptic products containing povidone-iodine 5 to 10 percent submitted to the OTC Drug Review were health care personnel hand washes and surgical hand scrubs intended to be used with water (Ref. 13). Povidone-iodine 5 to 10 percent has not been demonstrated to be eligible for the OTC Drug Review for evaluation as a health care personnel hand rub or surgical hand rub, and we propose to categorize povidone-iodine for these uses as a new drug. However, povidone-iodine has been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash, surgical hand scrub, and patient preoperative skin preparation (59 FR 31402 at 31423 and 31435–31436). Thus, we include a discussion of the safety and effectiveness of povidone iodine for these uses in this proposed rule.

5. Mercufenol Chloride

Mercufenol chloride was evaluated for use only as a patient preoperative skin preparation in the 1994 TFM (59 FR 31402 at 31428–31429 and 31435–31436). Based on the information we currently have about eligibility, we propose to categorize as a new drug mercufenol chloride for use as a health care personnel hand wash or rub or as a surgical hand scrub or rub. Mercufenol chloride, however, has been demonstrated to be eligible for the OTC Drug Review for use as a patient preoperative skin preparation.

6. Polyhexamethylene Biguanide; Benzalkonium Cetyl Phosphate; Cetylpyridinium Chloride; Salicylic Acid; Sodium Hypochlorite; Tea Tree Oil; Combination of Potassium Vegetable Oil Solution, Phosphate Sequestering Agent, and Triethanolamine

Following the publication of the 1994 TFM, FDA received submissions for the first time requesting that polyhexamethylene biguanide; benzalkonium cetyl phosphate; cetylpyridinium chloride; salicylic acid; sodium hypochlorite; tea tree oil; and the combination of potassium vegetable oil solution, phosphate sequestering agent, and triethanolamine be added to the monograph (Refs. 14 through 19). These compounds were not addressed in prior FDA documents related to the monograph and were not evaluated for any health care antiseptic use by the Antimicrobial I Panel. The submissions received by FDA to date do not include documentation demonstrating the eligibility of any of these seven compounds for inclusion in the monograph (Ref. 20). Therefore, polyhexamethylene biguanide, benzalkonium cetyl phosphate, cetylpyridinium chloride, salicylic acid, sodium hypochlorite, tea tree oil, and the combination of potassium vegetable oil solution, phosphate sequestering agent, and triethanolamine have not been demonstrated to be eligible for the OTC Drug Review. Based on the information we currently have about eligibility, we propose to categorize these compounds as new drugs and we do not include a discussion of safety or effectiveness data submitted for them in this proposed rule.

7. Other Individual Active Ingredients

In the 1994 TFM, each of the following ingredients was evaluated for use as a patient preoperative skin preparation, a health care personnel hand wash, and a surgical hand scrub (59 FR 31402 at 31435–31436):

- Benzethonium chloride
- Chloroxylenol
- Cloflucarban
- Fluorosalan
- Hexylresorcinol
- Methylbenzethonium chloride
- Phenol (less than 1.5 percent)
- Secondary amyltricresols
- Sodium oxychlorosene
- Triclocarban
- Triclosan

The only health care personnel hand wash or surgical hand scrub products containing any of these ingredients that were submitted to the OTC Drug Review were products that were intended to be used with water (*i.e.,* rinse-off products) (Ref. 13). Consequently, based on the information we currently have about eligibility, we propose to categorize as a new drug each of these ingredients for use as a health care personnel hand rub or a surgical hand rub, and we do not include a discussion of safety or effectiveness of these ingredients for these uses in this proposed rule.

Each of the listed ingredients, however, has been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash, surgical hand scrub, and patient preoperative skin preparation.

8. Combination Active Ingredients

The combination active ingredients (1) calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative; (2) mercufenol chloride and secondary amyltricresols in 50 percent alcohol; and (3) triple dye have not been demonstrated to be eligible for the OTC Drug Review for use as a health care personnel hand wash or rub or as a surgical hand scrub or rub (59 FR 31402 at 31435–31436). Consequently, based on the information we currently have about eligibility, we propose to categorize as a new drug each of these ingredients for use as a health care personnel hand wash, health care personnel hand rub, surgical hand scrub, or a surgical hand rub, and we do not include a discussion of safety or effectiveness of these ingredients for these uses in this proposed rule. However, each of the previously discussed active ingredients has been demonstrated to be eligible for the OTC Drug Review for use as a patient preoperative skin preparation.

## IV. Ingredients Previously Proposed as Not Generally Recognized as Safe and Effective

FDA may determine that an active ingredient is not GRAS/GRAE for a given OTC use (*i.e.,* nonmonograph) because of lack of evidence of effectiveness, lack of evidence of safety, or both. In the 1994 TFM (59 FR 31402 at 31435–31436), FDA proposed that the active ingredients fluorosalan, hexachlorophene, phenol (greater than 1.5 percent), and tribromsalan be found not GRAS/GRAE for the uses referred to in the 1994 TFM as antiseptic hand wash and health care personnel hand wash. FDA did not classify hexachlorophene or tribromsalan in the 1978 TFM (43 FR 1210 at 1227) because it had already taken final regulatory action against hexachlorophene (21 CFR 250.250) and certain halogenated salicylamides, notably tribromsalan (21 CFR 310.502). No substantive comments

or new data were submitted to the record of the 1994 TFM to support reclassification of any of these ingredients to GRAS/GRAE status. Therefore, FDA is continuing to propose that these active ingredients be found not GRAS/GRAE for OTC health care antiseptic products as defined in this proposed rule and that any OTC health care antiseptic drug product containing any of these ingredients not be allowed to be introduced or delivered for introduction into interstate commerce unless it is the subject of an approved application, effective, except as otherwise provided in other regulations, as of 1 year after publication of the final monograph in the **Federal Register**.

## V. Summary of Proposed Classifications of OTC Health Care Antiseptic Active Ingredients

Tables 4 through 7 in this proposed rule list the classification proposed in the 1994 TFM for each OTC health care antiseptic active ingredient according to intended use and the classification being proposed in this proposed rule. The specific data that has been submitted to the public docket (the rulemaking) and evaluated by FDA and the description of data still lacking in the administrative record is later described in detail for each active ingredient for which we have some data in section VII.D.

Tables 4 and 5 list ingredients for which a different status is being proposed in this proposed rule than was proposed in the 1994 TFM.

TABLE 4—CLASSIFICATION OF OTC HEALTH CARE PERSONNEL HAND WASH AND SURGICAL HAND SCRUB ANTISEPTIC ACTIVE INGREDIENTS IN THIS PROPOSED RULE AND IN THE 1994 TFM

| Active ingredient | 1994 TFM | This proposed rule |
|---|---|---|
| Alcohol 60 to 95 percent | I [1] | IIISE [2] |
| Hexylresorcinol | IIIE | IIISE |
| Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate) | IIIE | IIISE |
| Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol) | IIIE | IIISE |
| Isopropyl alcohol 70 to 91.3 percent | IIIE | IIISE |
| Nonylphenoxypoly (ethyleneoxy) ethanoliodine | IIIE | IIISE |
| Poloxamer iodine complex | IIIE | IIISE |
| Povidone-iodine 5 to 10 percent | I | IIISE |
| Secondary amyltricresols | IIIE | IIISE |
| Triclocarban | IIIE | IIISE |
| Undecoylium chloride iodine complex | IIIE | IIISE |

[1] "I" denotes a classification that an active ingredient has been shown to be safe and effective.
[2] "III" denotes a classification that additional data are needed. "S" denotes safety data needed. "E" denotes effectiveness data needed.

TABLE 5—CLASSIFICATION OF OTC PATIENT PREOPERATIVE SKIN PREPARATION ANTISEPTIC ACTIVE INGREDIENTS IN THIS PROPOSED RULE AND IN THE 1994 TFM

| Active ingredient | 1994 TFM | This proposed rule |
|---|---|---|
| Alcohol 60 to 95 percent | I [1] | IIISE [2] |
| Benzalkonium chloride | IIIE | IIISE |
| Benzethonium chloride | IIIE | IIISE |
| Chloroxylenol | IIIE | IIISE |
| Hexylresorcinol | IIIE | IIISE |
| Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol) | IIIE | IIISE |
| Iodine tincture USP | I | IIISE |
| Iodine topical solution USP | I | IIISE |
| Isopropyl alcohol 70 to 91.3 percent | I | IIISE |
| Mercufenol chloride | IIIE | IIISE |
| Methylbenzethonium chloride | IIIE | IIISE |
| Nonylphenoxypoly (ethyleneoxy) ethanoliodine | IIIE | IIISE |
| Phenol (less than 1.5 percent) | IIIE | IIISE |
| Poloxamer iodine complex | IIIE | IIISE |
| Povidone-iodine 5 to 10 percent | I | IIISE |
| Triclocarban | IIIE | IIISE |
| Triclosan | IIIE | IIISE |
| Undecoylium chloride iodine complex | IIIE | IIISE |

[1] "I" denotes a classification that an active ingredient has been shown to be safe and effective.
[2] "III" denotes a classification that additional data are needed. "S" denotes safety data needed. "E" denotes effectiveness data needed.

This proposed rule does not change the status of a number of antiseptic active ingredients previously proposed as lacking sufficient evidence of safety or effectiveness or the status of several ingredients previously proposed as having been shown to be unsafe, ineffective, or both (see tables 6 and 7).

TABLE 6—OTC HEALTH CARE PERSONNEL HAND WASH AND SURGICAL HAND SCRUB ANTISEPTIC ACTIVE INGREDIENTS WITH NO CHANGE IN CLASSIFICATION IN THIS PROPOSED RULE COMPARED TO THE 1994 TFM

| Active ingredient | No change in classification |
|---|---|
| Benzalkonium chloride | IIISE [1] |
| Benzethonium chloride | IIISE |
| Chloroxylenol | IIISE |
| Cloflucarban | IIISE/II [2] |
| Fluorosalan | II [3] |
| Hexachlorophene | II |
| Methylbenzethonium chloride | IIISE |
| Phenol (less than 1.5 percent) | IIISE |
| Phenol (greater than 1.5 percent) | II |
| Sodium oxychlorosene | IIISE |
| Tribromsalan | II |
| Triclosan | IIISE |

[1] "III" denotes a classification that additional data are needed. "S" denotes safety data needed. "E" denotes effectiveness data needed.

[2] Health care personnel hand wash proposed as IIISE and surgical hand scrub proposed as II.

[3] "II" denotes a classification that an active ingredient has been shown to be unsafe, ineffective, or both.

TABLE 7—OTC PATIENT PREOPERATIVE SKIN PREPARATION ANTISEPTIC ACTIVE INGREDIENTS WITH NO CHANGE IN CLASSIFICATION IN THIS PROPOSED RULE COMPARED TO THE 1994 TFM

| Active ingredient | No change in classification |
|---|---|
| Cloflucarban | II [1] |
| Fluorosalan | II |
| Hexachlorophene | II |
| Phenol (greater than 1.5 percent) | II |
| Secondary amyltricresols | IIISE [2] |
| Sodium oxychlorosene | IIISE |
| Tribromsalan | II |
| Calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative. | II |
| Mercufenol chloride and secondary amyltricresols in 50 percent alcohol. | IIISE |
| Triple dye | II |

[1] "II" denotes that an active ingredient has been shown to be unsafe, ineffective, or both.

[2] "III" denotes a classification that additional data are needed. "S" denotes safety data needed. "E" denotes effectiveness data needed.

## VI. Effectiveness (Generally Recognized as Effective) Determination

OTC regulations (§§ 330.10(a)(4)(ii) and 314.126(b)) define the standards for establishing that an OTC drug containing a particular active ingredient would be GRAE for its intended use. These regulations provide that supporting investigations must be adequate and well-controlled, and able to distinguish the effect of a drug from other influences such as a spontaneous change in the course of the disease, placebo effect, or biased observation. In general, such investigations include controls that are adequate to provide an assessment of drug effect, are adequate measures to minimize bias, and use adequate analytical methods to demonstrate effectiveness. For active ingredients being evaluated in the OTC Drug Review, this means that a demonstration of the contribution of the active ingredient to any effectiveness observed is required before an ingredient can be determined to be GRAE for OTC drug use.

In the 1994 TFM, we proposed a log reduction standard (a clinical simulation standard) for establishing effectiveness of consumer and health care antiseptics (59 FR 31402 at 31448) for the proposed intended use of decreasing bacteria on the skin. The 1994 TFM log reduction standard for effectiveness is based on a surrogate endpoint (*i.e.,* number of bacteria removed from the skin), rather than a clinical outcome (*e.g.,* reduction in the number of infections). In accordance with recommendations made by NDAC at its March 2005 meeting, we continue to propose a log reduction standard to demonstrate the general recognition of effectiveness of health care antiseptic active ingredients. See section VI.B for our current proposed log reduction standard.

Unlike the use of antiseptics in the consumer setting, the use of antiseptics by health care providers in the hospital setting is considered an essential component of hospital infection control measures (Refs. 21, 22, and 23). Hospital-acquired infections can result in prolonged hospital stays, additional medical treatment, adverse clinical outcomes, and increased health care costs (Refs. 24 through 27). The reliance on antiseptics in the clinical setting goes back over 150 years when, in the mid-1800s, Semmelweis observed that the mortality associated with childbed fever at the General Hospital in Vienna could be reduced by disinfection of physicians' hands with chlorine prior to patient care (Ref. 28). Around the same time, Lister demonstrated the effect of skin disinfection on surgical site infection rates (Ref. 28). This observational evidence of the effect of antiseptics on infection by Semmelweis and Lister form the basis for the current role of antiseptics as a critical component of hospital infection control procedures. Adequate and well-controlled clinical trials demonstrating a definitive link between antiseptic use and a reduction in infection rates are lacking, however.

The March 2005 NDAC acknowledged the difficulty in designing clinical trials to demonstrate the impact of health care antiseptics on infection rates. This difficulty was one reason the committee advised against clinical outcome trials to demonstrate the effectiveness of health care antiseptics. Numerous factors contribute to hospital-acquired infections and, therefore, would need to be controlled for in the design of these types of studies. For example, some of the known risk factors for surgical site infection that must be controlled for include the following: Patient age, nutritional status, diabetes, smoking, obesity, coexistent infections at a remote body site, colonization with microorganisms, altered immune response, length of preoperative stay, duration of surgical scrub, preoperative shaving, preoperative skin prep, duration of the operation, inadequate sterilization of instruments, foreign material in the surgical site, surgical drain, and surgical technique (Ref. 22). There are also standard infection control measures such as gloving, isolation procedures, sterilization of instruments, and waste disposal that make it difficult to demonstrate the independent contribution of antiseptics to the reduction of the risk of hospital infection (Ref. 28).

Although we found a few studies that could serve as a basis for designing a clinical outcome study in the consumer setting (78 FR 76444 at 76450), we have not found any acceptable clinical outcome study designs for health care antiseptics. The March 2005 NDAC recommended that sponsors perform an array of trials to look simultaneously at the effect on the surrogate endpoint and the clinical endpoint to try to establish a link between the surrogate and clinical endpoints, but provided no guidance on possible study designs. We have not seen any studies of this type. The March 2005 NDAC also believed that it would be unethical to perform a hospital trial using a vehicle control instead of an antiseptic. Although the NDAC thought

that performing a placebo-controlled study for routine patients on the ward might be feasible, it stated that the Centers for Disease Control and Prevention hand hygiene guidelines and hospital accreditation requirements would prohibit such a practice. The NDAC also believed that an institutional review board would not approve a hospital trial that did not involve an antiseptic.

We agree that a clinical outcome study in the health care setting raises ethical concerns. For a clinical outcome study to be adequately controlled the study design would need to include a vehicle or negative control arm. However, the inclusion of such control arms in a clinical outcome study conducted in a hospital setting could pose an unacceptable health risk to study subjects (hospitalized patients and health care providers). In such studies a vehicle or negative control would be a product with no antimicrobial activity. The use of a nonantimicrobial product in a hospital setting (a setting with an already elevated risk of infections) could increase the risk of infection for both health care providers and their patients. Thus, it is generally considered unethical to perform placebo-controlled clinical studies to show the value of health care antiseptics (Ref. 8). Based on these considerations NDAC recommended the continued use of clinical simulation studies to validate the effectiveness of health care antiseptics.

FDA has relied upon clinical simulation studies to support the approval of health care antiseptics through the NDA process. Although it is not possible to quantify the contribution of NDA health care antiseptics to reduced hospital infection rates, in general, infection rates in the United States are low. For example, only 2 to 5 percent of over 40 million inpatient surgical procedures each year are complicated by surgical site infections (Ref. 29). We acknowledge that the use of surrogate endpoints to assess the effectiveness of these products is not optimal, but we believe it is the best means available of assessing the effectiveness of health care antiseptic products.

Thus, we are continuing to rely on surrogate endpoints to evaluate the effectiveness of health care antiseptics while requiring data from clinical outcome studies to support the effectiveness of consumer antiseptics (78 FR 76444 at 76450). Unlike consumer antiseptics, however, health care antiseptics are considered an integral part of hospital infection control strategies (Refs. 21, 23, and 30). As is the case for consumer antiseptics, we lack clinical outcome data from adequate studies demonstrating the impact of health care antiseptics on infection rates. Given this, FDA faces the challenge of regulating this important component of current hospital infection control measures without methods to directly assess their clinical effect. We nonetheless need a practical means to assess the general recognition of effectiveness of health care products, such as the clinical simulation studies.

As discussed in section VI.A, we evaluated all the available effectiveness studies for health care antiseptics (*i.e.,* health care personnel hand washes and rubs, surgical hand scrubs and rubs, and patient preoperative skin preparations) to determine whether the data supported finding the health care antiseptic active ingredient to be GRAE based on the 1994 TFM effectiveness criteria (which we are now proposing to update). We found that the available studies are not adequate to support a GRAE determination for any health care antiseptic active ingredient under the 1994 TFM effectiveness criteria (59 FR 31402 at 31445, 31448, and 31450).[2]

*A. Evaluation of Effectiveness Data*

1. Clinical Simulation Studies

Most of the data available to support the effectiveness of health care antiseptics are based on clinical simulation studies, such as the ones described in the 1994 TFM (59 FR 31402 at 31444). In vivo test methods, such as clinical simulation studies, and evaluation criteria proposed in the 1994 TFM are based on the premise that bacterial reductions achieved using tests that simulate conditions of actual use for each OTC health care antiseptic product category reflect the bacterial reductions that would be achieved under conditions of such use. For example, one of the intended purposes of a health care personnel hand wash is to reduce the risk of patient-to-patient cross contamination. Thus, the clinical simulation studies proposed in the 1994 TFM are designed to demonstrate effectiveness of a product in the presence of repeated bacterial challenge. The hands are artificially contaminated with a marker organism (bacteria), and the reduction from the baseline numbers of the contaminating organism is determined after use of the test product. This contamination and hand wash procedure is repeated several times, and bacterial reductions are measured at various time points. This aspect of the study design is intended to mimic the repeated use of the product (59 FR 31402 at 31448).

The testing proposed in the 1994 TFM for surgical hand scrubs and patient preoperative skin preparations involves testing against resident skin microflora (bacteria that normally colonize the skin), and there is no artificial contamination of the skin in these studies. Testing demonstrates that the resident bacterial load is highly variable among individuals within the general population (Refs. 31 and 32). Although the 1994 TFM methods specify a minimum bacterial count for individuals to be included in the assessment of surgical hand scrubs and patient preoperative skin preparations, there can be considerable intersubject variability. Similar to the health care personnel hand washes, the testing of a surgical hand scrub proposed in the 1994 TFM involves multiple test product uses and the repeated measurement of bacterial reductions to determine both immediate and persistent antimicrobial activity (59 FR 31402 at 31445). The patient preoperative skin preparation test evaluates a single application of the product on a dry skin site (abdomen or back) and a moist skin site (groin or axilla) with higher numbers of resident bacteria (59 FR 31402 at 31450). The effectiveness criteria for patient preoperative skin preparations and surgical hand scrubs proposed in the 1994 TFM also require that bacterial growth be suppressed for 6 hours (59 FR 31402 at 31445 and 31450).

We evaluated all clinical simulation studies that were submitted to the OTC Drug Review for evidence of health care personnel hand antiseptic, surgical hand antiseptic, and patient preoperative skin preparation effectiveness demonstrated under the log reduction criteria proposed in the 1994 TFM (59 FR 31402 at 31445, 31448, and 31450) (Ref. 33). We also searched the published literature for clinical simulation studies that assess health care personnel hand antiseptic, surgical hand antiseptic, and patient preoperative skin preparation effectiveness using the log reduction criteria in the 1994 TFM (Refs. 33 through 36).

Overall, the studies used a variety of study designs, including nonstandard study designs. In some cases, such as for surgical hand antiseptics, data submitted to the OTC Drug Review was

[2] We note that alcohol, isopropyl alcohol, and some iodine-containing active ingredients were proposed as GRAE in the 1994 TFM; however, the studies that supported that proposal do not meet our current standards for adequate and well-controlled studies. See discussion in section VI.A.1.

in the form of abstracts and technical reports. There is insufficient information to evaluate the scientific merit of studies described in abstracts and technical reports. Most importantly, none of the evaluated studies were adequately controlled to demonstrate the contribution of the active ingredient to the effectiveness observed in the studies (43 FR 1210 at 1240) and, therefore, cannot be used to demonstrate that the active ingredient tested is GRAE.

In general, the evaluated studies also had other deficiencies. Each study had at least one of the following deficiencies:

- Some studies that were described as using a standardized method (American Society for Testing and Materials (ASTM) or 1994 TFM) varied from these methods without explanation or validation, and the majority of studies did not provide sufficient information about critical aspects of the study conduct.
- Many studies did not include appropriate controls; for example, some studies did not include a vehicle control or an active control (59 FR 31402 at 31446, 31448, and 31450), and some studies that included an active control failed to use the control product according to its labeled directions (59 FR 31402 at 31446, 31448, and 31450).
- Many studies did not provide sufficient detail concerning neutralizer use (43 FR 1210 at 1244) or validation of neutralizer effectiveness.
- The studies evaluated a small number of subjects (59 FR 31402 at 31446, 31449, and 31451).
- Some studies did not sample at all of the time points specified by the test method (59 FR 31402 at 31446, 31448, and 31450).
- In the case of patient preoperative skin preparation studies, some studies used subjects with baseline values that were too low and other studies did not provide baseline values at all (59 FR 31402 at 31451). Many of the studies only tested one type of test site (dry or moist), but the 1994 TFM (as well as the testing proposed here) requires testing of both dry and moist test sites to demonstrate effectiveness (59 FR 31402 at 31450).

FDA's detailed evaluation of the data is filed in Docket No. FDA–2015–N–0101, available at *http://www.regulations.gov* (Refs. 33 through 36).

2. Clinical Outcome Studies

Although we are not currently proposing to require clinical outcome studies to support a GRAE determination in this proposal, FDA has evaluated all the clinical outcome studies that were submitted to the OTC Drug Review to look for evidence of a clinical benefit from the use of health care antiseptics (Ref. 33). In addition, we searched the published literature for clinical outcome studies that would provide evidence of a clinical benefit from the use of a health care antiseptic (Ref. 37). Most of these studies were designed to evaluate health care worker compliance with hand hygiene protocols, and thus, were not adequately controlled to demonstrate a reduction of infection rates. Most importantly, none of the studies used a vehicle control. In general, the studies had additional design flaws such as the following:

- A small sample size.
- A lack of randomization, blinding, or both.
- Inadequate statistical power and, in some cases, a failure to analyze results for statistical significance.
- Inadequate description of methodology and data collection methods.
- Inadequate documentation of proper training in hand wash or rub, surgical hand scrub or rub, or patient preoperative skin preparation technique.
- Failure to observe and document hand washing technique.
- Inadequate controls to address the multifactorial nature of surgical site infection.
- Some patients received antibiotic treatment and others did not.
- Some studies addressed nonmonograph indications.

As discussed in section VI, the March 2005 NDAC agreed that there are currently no clinical trials presented that showed any clinical benefit. The committee stated that conducting such a study in the hospital setting would be unethical, especially considering the need to introduce a placebo or vehicle control to show contribution of an antiseptic drug product. This would put the subjects' health at risk.

*B. Current Standards: Studies Needed To Support a Generally Recognized as Effective Determination*

In the 1994 TFM, we proposed that the effectiveness of antiseptic active ingredients could be supported by a combination of in vitro studies and in vivo clinical simulation testing as described in 21 CFR 333.470 (59 FR 31402 at 31444). In vitro studies are designed to demonstrate the product's spectrum and kinetics of antimicrobial activity, as well as the potential for the development of resistance associated with product use. In vivo test methods and evaluation criteria are based on the premise that bacterial reductions can be adequately demonstrated using tests that simulate conditions of actual use for each OTC health care antiseptic product category and that those reductions are reflective of bacterial reductions that would be achieved during use. (See discussion in section B.2.) Given the limitations of our ability to study these active ingredients in a clinical outcome study in a health care setting, a GRAE determination for a health care antiseptic active ingredient should be supported by an adequate characterization of the antimicrobial activity of the ingredient through both in vitro testing and in vivo clinical simulation testing.

1. In Vitro Studies

The 1994 TFM proposed that the antimicrobial activity of an active ingredient could be demonstrated in vitro by a determination of the in vitro spectrum of antimicrobial activity, minimum inhibitory concentration (MIC) testing against 25 fresh clinical isolates and 25 laboratory strains, and time-kill testing against 23 laboratory strains (59 FR 31402 at 31444). Comments received in response to the 1994 TFM objected to the proposed in vitro testing requirements, stating that they were overly burdensome (Ref. 38). Consequently, submissions of in vitro data submitted to support the effectiveness of antiseptic active ingredients were far less extensive than what was proposed in the 1994 TFM (Ref. 39). Although we agree that the in vitro testing proposed in the 1994 TFM is overly burdensome for testing every final formulation of an antiseptic product that contains a GRAE ingredient, we continue to believe that a GRAE determination for a health care antiseptic active ingredient should be supported by adequate in vitro characterization of the antimicrobial activity of the ingredient. In addition, we now propose the option of assessing the minimum bactericidal concentration (MBC) as an alternative to testing the MIC to demonstrate the broad spectrum activity of the antiseptic. The ability of an antiseptic to kill microorganisms, rather than inhibit them, is more relevant for a topical product. Because the determination of GRAE status is a very broad statement that can apply to many different formulations of an active ingredient, we continue to propose that an evaluation of the spectrum and kinetics of antimicrobial activity of a health care antiseptic active ingredient should include the following:

- A determination of the in vitro spectrum of antimicrobial activity against recently isolated normal flora

and cutaneous pathogens (59 FR 31402 at 31444).

• MIC or MBC testing of 25 representative clinical isolates and 25 reference (*e.g.,* American Type Culture Collection) strains of each of the microorganisms listed in the 1994 TFM (59 FR 31402 at 31444).

• Time-kill testing of each of the microorganisms listed in the 1994 TFM (59 FR 31402 at 31444) to assess how rapidly the antiseptic active ingredient produces its effect. The dilutions and time points tested should be relevant to the actual use pattern of the final product.

Despite the fact that the in vitro data submitted to support the effectiveness of antiseptic active ingredients were far less extensive than proposed in the 1994 TFM, manufacturers may have data of this type on file from their own product development programs that has not been submitted to the rulemaking. Furthermore, published data may be available that would satisfy some or all of this data requirement.

2. In Vivo Studies

Based on the recommendations of NDAC at its March 23, 2005, meeting, we are continuing to propose the use of bacterial log reductions as a means of demonstrating that health care antiseptics are GRAE (Ref. 8). The 1994 TFM also proposed final formulation testing for health care personnel hand washes (59 FR 31402 at 31448), surgical hand scrubs (59 FR 31402 at 31445), and patient preoperative skin preparations (59 FR 31402 at 31450). We do not discuss final formulation testing here because we are not proposing that any of the active ingredients are GRAS/GRAE. Although these proposed test methods are intended to evaluate the effectiveness of antiseptic final formulations, this type of clinical simulation testing when adequately controlled also can be used to demonstrate that an active ingredient is GRAE for use in a health care antiseptic product. Based on our experience with the approval of NDA antiseptic products and input from the March 2005 NDAC, we recommend that the bacterial log reduction studies used to demonstrate that an active ingredient is GRAE for use in health care antiseptic drug products include the following:

• A vehicle control to show the contribution of the active ingredient to effectiveness. The test product should be statistically superior to the vehicle control for the clinical simulation to be considered successful at showing that the test product is effective for use in health care antiseptic products. Products with vehicles that have antimicrobial activity should consider using a negative control, such as nonantimicrobial soap or saline, rather than a vehicle control.

• An active control to validate the study conduct to assure that the expected results are produced. For the results to be valid, the active control should meet the appropriate log reduction criteria.

• A sample size large enough to show statistically significant differences from the results achieved using the vehicle, and meeting the threshold of at least a 70 percent success rate for the health care antiseptic, including justification that the number of subjects tested is adequate for the test.

• Use of an appropriate neutralizer in all recovery media (*i.e.,* sampling solution, dilution fluid, and plating media) and a demonstration of neutralizer validation. The purpose of neutralizer validation is to show that the neutralizer used in the study is effective against the test and control products, and that it is not toxic to the test microorganisms. If a test product can be neutralized through dilution, this should be demonstrated in the neutralizer validation study.

• An analysis of the proportion of subjects who meet the log reduction criteria based on a two-sided statistical test for superiority to vehicle and a 95 percent confidence interval approach.

To establish that a particular active ingredient is GRAE for use in health care antiseptics, clinical simulation studies using the parameters described in this section should be evaluated using log reduction criteria similar to those proposed in the 1994 TFM (59 FR 31402 at 31445, 31448, and 31450). Our current criteria are laid out in table 8. We have revised the log reduction criteria proposed for health care personnel hand washes and rubs, and surgical hand scrubs and rubs based on the recommendations of the March 2005 NDAC and comments to the 1994 TFM that argued that the demonstration of a cumulative antiseptic effect for these products is unnecessary. We agree that the critical element of effectiveness is that a product must be effective after the first application because that represents the way in which health care personnel hand washes and rubs and surgical hand scrubs and rubs are used. For these indications, log reduction criteria are proposed only for a single-product application rather than multiple-product applications. Given that we are no longer requiring a cumulative antiseptic effect, the log reduction criteria were revised to reflect this single product application and fall between the log reductions previously proposed for the first and last applications. The GRAE criteria proposed for all the health care antiseptic indications are based on log reductions achieved by antiseptics as shown in the published literature and evaluated under the NDA process. In addition, based on the timeframes within which patient preoperative skin preparations are commonly used, we are recommending that these products also be able to demonstrate effectiveness at 30 seconds because we believe that injections and some incisions might be made as soon as 30 seconds after skin preparation. The log reductions that we would expect an effective health care antiseptic active ingredient to meet to show that it is GRAE are shown in table 8.

TABLE 8—CLINICAL SIMULATION TESTING BACTERIAL LOG REDUCTION EFFECTIVENESS CRITERIA IN THIS PROPOSED RULE AND IN THE 1994 TFM

| Indication | 1994 TFM | This proposed rule |
|---|---|---|
| Health care personnel hand wash or health care personnel hand rub. | • reduction of 2 $\log_{10}$ on each hand within 5 minutes after the first wash, and<br>• reduction of 3 $\log_{10}$ on each hand within 5 minutes after the tenth wash. | reduction of 2.5 $\log_{10}$ on each hand within 5 minutes after a single wash or rub. |

TABLE 8—CLINICAL SIMULATION TESTING BACTERIAL LOG REDUCTION EFFECTIVENESS CRITERIA IN THIS PROPOSED RULE AND IN THE 1994 TFM—Continued

| Indication | 1994 TFM | This proposed rule |
|---|---|---|
| Surgical hand scrub or surgical hand rub | • reduction of 1 $\log_{10}$ on each hand within 1 minute after the first wash on day 1, and<br>• does not exceed baseline at 6 hours on day 1, and.<br>• reduction of 2 $\log_{10}$ on each hand within 1 minute after the last wash on day 2, and<br>• reduction of 3 $\log_{10}$ on each hand within 1 minute after the last wash on day 5. | • reduction of 2 $\log_{10}$ on each hand within 1 minute after a single wash or rub, and<br>• does not exceed baseline at 6 hours. |
| Patient preoperative skin preparation | • reduction of 2 $\log_{10}$ per square centimeter on abdominal site within 10 minutes after use, and<br>• reduction of 3 $\log_{10}$ per square centimeter on groin site within 10 minutes after use, and<br>• does not exceed baseline at 6 hours | • reduction of 2 $\log_{10}$ per square centimeter on abdominal site within 30 seconds after use, and<br>• reduction of 3 $\log_{10}$ per square centimeter on groin site within 30 seconds after use, and<br>• does not exceed baseline at 6 hours. |

## VII. Safety (Generally Recognized as Safe) Determination

In the 1994 TFM, 11 active ingredients were classified as GRAS for both health care personnel hand wash and surgical hand scrub use, and 18 active ingredients were classified as GRAS for patient preoperative skin preparation use (59 FR 31402 at 31435). As described in section I.C., health care personnel hand rubs and surgical hand rubs were not separately addressed in the 1994 TFM. There have since been a number of important scientific developments affecting our evaluation of the safety of these active ingredients and causing us to reassess the data necessary to support a GRAS determination. There is now new information regarding systemic exposure to antiseptic active ingredients (Refs. 1 through 5). The potential for widespread antiseptic use to promote the development of antibiotic-resistant bacteria also needs to be evaluated. Further, additional experience with and knowledge about safety testing has led to improved testing methods. Improvements include study designs that are more capable of detecting potential safety risks. Based on our reassessment, we are proposing new GRAS data standards for health care antiseptic active ingredients. In order to fully address these new safety concerns, additional safety data will be necessary to support a GRAS determination for all health care antiseptic active ingredients.

Many of the safety considerations for the five health care antiseptic uses are the same because each use is considered a ''chronic'' use as that term is defined by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).[3] A use is considered chronic if the drug will be used for a period of at least 6 months over the user's lifetime, including repeated, intermittent use (Ref. 40). Health care personnel washes and rubs are used on a frequent daily basis, as are surgical hand scrubs and rubs. Health care authorities list a variety of situations in which health care workers should perform hand hygiene, such as before and after touching a patient, after contact with body fluids, and after removing gloves (Refs. 21 and 23). Patient preoperative skin preparations also are used daily by many users. For example, many people with type I diabetes require three to four insulin injections a day (Ref. 41) and use these products prior to each injection. Accordingly, we are proposing the same safety testing for each active ingredient be done to support a GRAS determination, regardless of the proposed health care antiseptic use.

### *A. New Issues*

Since the 1994 TFM was published, new data have become available indicating that systemic exposure to topical antiseptic active ingredients may be greater than previously thought. Systemic exposure refers to the presence of antiseptic active ingredients inside and throughout the body. Because of advances in technology, our ability to detect antiseptic active ingredients in body fluids such as serum and urine is greater than it was in 1994. For example, studies have shown detectable blood alcohol levels after use of alcohol-containing health care personnel hand rubs or surgical hand rubs (Refs. 1, 4, and 5). We believe that any consequences of this systemic exposure should be identified and assessed to support our risk-benefit analysis for health care antiseptic use.

Given the frequent repeated use of both health care personnel hand washes and rubs and surgical hand scrubs and rubs, systemic exposure may occur. For some patients, the same may be true for patient preoperative skin preparations. Although some systemic exposure data exist for alcohol and triclosan, many of the other health care antiseptic active ingredients have not been evaluated in this regard. Currently, there is also a lack of data to assess the impact of important drug use factors that can influence systemic exposure such as dose, application frequency, application method, duration of exposure, product formulation, skin condition, and age.

The evaluation of the safety of drug products involves correlating findings from animal toxicity studies to the level of drug exposure obtained from pharmacokinetic studies in animals and humans. Our administrative record lacks the data necessary to define a margin of safety for the potential chronic use of health care antiseptic active ingredients. Thus, we are continuing to propose that both animal and human pharmacokinetic data are necessary for health care antiseptic active ingredients. This information will help identify any potential safety concerns and help determine the safety margin for OTC human use.

One potential effect of systemic exposure to health care antiseptic active ingredients that has come to our attention since publication of the 1994 TFM is data suggesting that some health care antiseptic active ingredients have hormonal effects. Triclosan and triclocarban can cause alterations in

[3] FDA is a member of the ICH Steering Committee, the governing body that oversees the harmonization activities, and contributed to the development of ICH guidelines.

thyroid and reproductive systems of neonatal and adolescent animals (Refs. 42 through 51). Hormonally active compounds have been shown to affect not only the exposed organism, but also subsequent generations (Ref. 52). These effects may not be related to direct deoxyribonucleic acid (DNA) mutation, but rather to alterations in factors that regulate gene expression (Ref. 53).

A hormonally active compound that causes reproductive system disruption in the fetus or infant may have effects that are not apparent until many years after initial exposure. There are also critical times in fetal development when a change in hormonal balance that would not cause any lasting effect in an adult could cause a permanent developmental abnormality in a child. For example, untreated hypothyroidism during pregnancy has been associated with cognitive impairment in the offspring (Refs. 54, 55, and 56).

Because health care antiseptics are chronic use products and are used by sensitive populations such as pregnant women, evaluation of the potential for chronic toxicity and effects on reproduction and development should be included in the safety assessment. The designs of general toxicity and reproductive/developmental studies are often sufficient to identify developmental effects that can be caused by hormonally active compounds through the use of currently accepted endpoints and standard good laboratory practice toxicology study designs. As followup in some cases, additional study endpoints may be needed to fully characterize the potential effects of drug exposure on the exposed individuals. Section VII.C describes the types of studies that can adequately evaluate an active ingredient's potential to cause developmental or reproductive toxicity, or adverse effects on the thyroid gland.

*B. Antimicrobial Resistance*

Since publication of the 1994 TFM, there is new information available concerning the impact of widespread antiseptic use on the development of antimicrobial resistance (Refs. 57 through 60). Bacteria use some of the same resistance mechanisms against both antiseptics and antibiotics. Thus, the use of antiseptic active ingredients with resistance mechanisms in common with antibiotics may have the potential to select for bacterial strains that are also resistant to clinically important antibiotics, adding to the problem of antibiotic resistance. In the health care setting where infection-control practices are multifaceted and include the use of antiseptics, antibiotics, and frequent disinfection, it is difficult to identify the source of antimicrobial resistance or to quantify the impact of antiseptics on the selection, survival, and spread of antimicrobial resistant bacterial strains.

Laboratory studies of some of the antiseptic active ingredients evaluated in this proposed rule demonstrate that bacteria can develop reduced susceptibility to antiseptic active ingredients and some antibiotics after growth in nonlethal amounts of the antiseptic (*i.e.,* low-to-moderate concentrations of antiseptic) (Refs. 61 through 78). These studies indicate that further data needs to be gathered regarding whether bacterial resistance mechanisms exist that could select for cross-resistance in the health care setting.

Laboratory studies examining the antiseptic and antibiotic susceptibilities of clinical isolates of *Staphylococcus aureus* and methicillin-resistant *S. aureus* (MRSA) have found strains of these organisms with reduced susceptibilities to both antiseptics and antibiotics (Refs. 67 and 79 through 83). However, the impact of such dual tolerances in the clinical setting is unclear. Studies of the impact of such tolerance in *S. aureus* and *Escherichia coli* in the clinical setting have yielded mixed results (Refs. 84 through 87). Interpretation of these data is further limited by the fact that only *S. aureus* and *E. coli* have been studied. All of the organisms studied constitute a very small subset of the organisms of concern, and one of these organisms (MRSA) is already resistant to some antimicrobials. Thus, the available data are not sufficient to support a finding that these mechanisms of reduced susceptibility would have meaningful clinical impact in a setting where extensive infection control measures that include antibiotic use and frequent disinfection are the norm. In other words, bacteria in the health care setting will be exposed to multiple sources of antimicrobials—regardless of the use of health care antiseptics—which may lessen the impact of the role of health care antiseptics in the development of bacterial resistance.

FDA has been evaluating the role that all antiseptic products, including health care antiseptic products, may play in the development of antibiotic resistance for quite some time, and has sought the advice from expert panels on this topic. In 1997, a joint Nonprescription Drugs and Anti-Infective Drugs Advisory Committee concluded that the data were not sufficient to take any action on this issue at that time (Ref. 6). The joint Committee recommended that FDA work with industry to establish surveillance mechanisms to address antiseptic and antibiotic resistance. FDA also plays a major role on the Interagency Task Force on Antimicrobial Resistance and helped draft the Public Health Action Plan to Combat Antimicrobial Resistance (Ref. 88). The Action Plan discusses how to sufficiently implement the surveillance, prevention and control, and research elements of the Action Plan.

Reports of the persistence of low levels of some antiseptic active ingredients in the environment (Refs. 89, 90, and 91) signal the need to better understand the impact of all antiseptics, including health care antiseptic drug products. Although it is important to consider the relative contribution of the use of health care antiseptic products to any possible environmental impact, it is also important to consider the benefits of these products. Hospital-acquired infections can result in prolonged hospital stays, additional medical treatment, adverse clinical outcomes, and increased health care costs. The use of health care antiseptics is considered an important component of the multifaceted approach that hospitals use to keep hospital acquired infection rates low (Refs. 21 and 23). Furthermore, in situations where there is extensive use of antibiotics, exposure to antibiotics, rather than exposure to antiseptics, plays a dominant role in emerging antibiotic resistance. This makes it difficult to determine whether antiseptics play a significant role in the development of antimicrobial resistance in the hospital setting. Despite this, the use of antiseptics in health care settings may also contribute to the selection of bacterial genera and species that are less susceptible to both antiseptics and antibiotics. We are requesting additional data and information to address this issue. Section VII.C describes the data that will help establish a better understanding of the interactions between antiseptic active ingredients and bacterial resistance mechanisms in health care antiseptic products and will provide the information needed to perform an adequate risk assessment for these health care product uses. FDA recognizes that the science of evaluating the potential of compounds to cause bacterial resistance is evolving and acknowledges the possibility that alternative data different from that listed in section VII.C may be identified as an appropriate substitute for evaluating resistance.

*C. Studies To Support a Generally Recognized as Safe Determination*

A GRAS determination for health care antiseptic active ingredients must be

supported by both nonclinical (animal) and clinical (human) studies. To issue a final monograph for these products, this safety data must be in the administrative record (*i.e.,* rulemaking docket).[4]

To assist manufacturers or others who wish to provide us with the information we expect will establish GRAS status for these active ingredients, we are including specific information, based in part on existing FDA guidance, about the other kinds of studies to consider conducting and submitting. We have published guidance documents describing the nonclinical safety studies that a manufacturer should perform when seeking to market a drug product under an NDA (Refs. 40 and 92 through 98). These guidance documents also provide relevant guidance for performing the nonclinical studies necessary to determine GRAS status for a health care antiseptic active ingredient. Because health care antiseptics may be used repeatedly and in sensitive populations, we propose that health care antiseptic active ingredients will need to be tested for carcinogenic potential, developmental and reproductive toxicity (DART), and other potential effects as described in more detail in this section.

1. FDA Guidances Describing Safety Studies

The safety studies that are described in the existing FDA guidances (Refs. 40 and 92 through 98) provide a framework for the types of studies that are needed for FDA to assess the safety of each antiseptic active ingredient according to modern scientific standards and make a GRAS determination. A description of each type of study and how we would use this information to improve our understanding of the safety of health care antiseptic active ingredients is provided in table 9.

TABLE 9—FDA GUIDANCE DOCUMENTS RELATED TO REQUESTED SAFETY DATA AND RATIONALE FOR STUDIES

| Type of study | Study conditions | What the data tell us | How the data are used |
|---|---|---|---|
| Animal pharmacokinetic absorption, distribution, metabolism, and excretion (ADME) (Refs. 93 and 99). | Both oral and dermal administration. | Allows identification of the dose at which the toxic effects of an active ingredient are observed as a result of systemic exposure of the drug. ADME data provide: The rate and extent an active ingredient is absorbed into the body (*e.g.*, AUC, Cmax, Tmax);[1] where the active ingredient is distributed in the body; whether metabolism of the active ingredient by the body has taken place; information on the presence of metabolites; and how the body eliminates the original active ingredient (parent) and its metabolites (*e.g.*, T½).[2]. | Used as a surrogate to identify toxic systemic exposure levels that can then be correlated to potential human exposure via dermal pharmacokinetic study findings. Adverse event data related to particular doses and drug levels (exposure) in animals are used to help formulate a safety picture of the possible risk to humans. |
| Human pharmacokinetics (MUsT) (Ref. 97). | Dermal administration using multiple formulations under maximum use conditions. | Helps determine how much of the active ingredient penetrates the skin, leading to measurable systemic exposure. | Used to relate the potential human exposure to toxic drug levels identified in animal studies. |
| Carcinogenicity (ICH S1A, S1B, and S1C (Refs. 40, 92, and 95)). | Minimum of one oral and one dermal study for topical products. | Provides a direct measure of the potential for active ingredients to cause tumor formation (tumorogenesis) in the exposed animals. | Identifies the systemic and dermal risks associated with drug active ingredients. Taken together, these studies are used to identify the type(s) of toxicity, the level of exposure that produces these toxicities, and the highest level of exposure at which no adverse effects occur, referred to as the ''no observed adverse effect level'' (NOAEL). The NOAEL is used to determine a safety margin for human exposure. |
| Developmental toxicity (ICH S5 (Ref. 94)). | Oral administration ..... | Evaluates the effects of a drug on the developing offspring throughout gestation and postnatally until sexual maturation. | |
| Reproductive toxicity (ICH S5 (Ref. 94)). | Oral administration ..... | Assesses the effects of a drug on the reproductive competence of sexually mature male and female animals. | |
| Hormonal effects (Ref. 98). | Oral administration ..... | Assesses the drug's potential to interfere with the endocrine system. | Used in hazard assessment to determine whether the drug has the capacity to induce a harmful effect at any exposure level without regard to actual human exposures. |

[1] ''AUC'' denotes the area under the concentration-time curve, a measure of total exposure or the extent of absorption. ''Cmax'' denotes the maximum concentration, which is peak exposure. ''Tmax'' denotes the time to reach the maximum concentration, which aids in determining the rate of exposure.

[2] ''T½'' denotes the half-life, which is the amount of time it takes to eliminate half the drug from the body or decrease the concentration of the drug in plasma by 50 percent.

These studies represent FDA's current thinking on the data needed to support a GRAS determination for an OTC antiseptic active ingredient and are similar to those recommended by the Antimicrobial I Panel (described in the ANPR (39 FR 33103 at 33135)) as updated by the recommendations of the 2014 NDAC. However, even before the 2014 NDAC meeting, the Panel's recommendations for data to support the safety of an OTC topical

[4] At the 2014 NDAC meeting, FDA received comments referencing data or other information that appears to be relevant to the safety assessment of health care antiseptic active ingredients, but the referenced data and information were not submitted to the docket for this rulemaking and we are not aware that it is otherwise publicly available. The Agency will consider only material that is submitted to the docket for this rulemaking or that is otherwise publicly available in its evaluation of the GRAS/GRAE status of a relevant ingredient. Information about how to submit such data or information to the docket is set forth in this document in the **ADDRESSES** section.

antimicrobial active ingredient included studies to characterize the following:

- Degree of absorption through intact and abraded skin and mucous membranes
- Tissue distribution, metabolic rates, metabolic fates, and rates and routes of elimination
- Teratogenic and reproductive effects
- Mutagenic and carcinogenic effects

2. Studies To Characterize Maximal Human Exposure

Because the available data indicate that some dermal products, including at least some antiseptic active ingredients, are absorbed after topical application in humans and animals, it is necessary to assess the effects of long-term dermal and systemic exposure to these ingredients. Based on input from the 2014 NDAC meeting, the Agency has also determined that results from a human pharmacokinetic (PK) maximal usage trial (MUsT) are needed to support a GRAS determination. This trial design is also referred to as a maximal use PK trial and is described in FDA's 2005 draft guidance for industry on developing drugs for treatment of acne vulgaris (Ref. 97). The purpose of the MUsT is to evaluate systemic exposure under conditions that would maximize the potential for drug absorption in a manner consistent with possible ''worst-case'' real world use of the product. In a MUsT, the collected plasma samples are analyzed, and the resulting in vivo data could be used to estimate a safety margin based on animal toxicity studies.

A MUsT to support a determination that an active ingredient is GRAS for use in health care antiseptics is conducted by obtaining an adequate number of PK samples following administration of the active ingredient. For studies of active ingredients to be used in topically applied products like these that are used primarily on adults, for which there is less information available and for which crossover designs are not feasible, a larger number of subjects are required compared to studies of orally administered drug products. A MUsT using 50 to 75 subjects should be sufficient to get estimates of the PK parameters from a topically applied health care antiseptic. The MUsT should attempt to maximize the potential for drug absorption to occur by considering the following design elements (Ref. 100):

- Adequate number of subjects (steps should be taken to ensure that the target population (for example, age, gender, race) is properly represented);
- frequency of dosing (*e.g.,* number of hand rub applications during the study);
- duration of dosing (*e.g.,* dosing to represent an 8- to 12-hour health care worker shift);
- use of highest proposed strength (*e.g.,* 95 percent alcohol);
- total involved surface area to be treated at one time (*e.g.,* hands and arms up to the elbow for surgical hand scrubs and rubs);
- amount applied per square centimeter
- method of application (*e.g.,* hand rub or hand wash); and
- sensitive and validated analytical methods.

It also is important that the MUsT reflect maximal use conditions of health care antiseptics (Ref. 101) using different formulations to fully characterize the active ingredient's potential for dermal penetration. Since real-world exposure from health care personnel hand wash and rub and surgical hand scrub and rub use is likely to be greater than from patient preoperative skin preparation use, MUsT data on an active ingredient for either of these indications also would be sufficient to fulfill the MUsT requirement for a patient preoperative skin preparation.

3. Studies To Characterize Hormonal Effects

We propose that data are also needed to assess whether health care antiseptic active ingredients have hormonal effects that could produce developmental or reproductive toxicity. A hormonally active compound is a substance that interferes with the production, release, transport, metabolism, binding, activity, or elimination of natural hormones, which results in a deviation from normal homeostasis, development, or reproduction (Ref. 102). Exposure to a hormonally active compound early in development can result in long-term or delayed effects, including neurobehavioral, reproductive, or other adverse effects.

There are several factors common to antiseptic products that make it necessary to assess their full safety profile prior to classifying an antiseptic active ingredient as GRAS for use in health care antiseptic products. These factors are as follows:

- Evidence of systemic exposure to several of the antiseptic active ingredients.
- Exposure to multiple sources of antiseptic active ingredients that may be hormonally active compounds, in addition to exposure to health care antiseptic products.
- Exposure to antiseptic active ingredients may be long-term for some health care professionals.

Most antiseptic active ingredients have not been evaluated for hormonal effects despite the fact that several of the ingredients have evidence of systemic absorption. For antiseptic active ingredients that have not been evaluated, in vitro receptor binding or enzyme assays can provide a useful preliminary assessment of the potential hormonal activity of an ingredient. However, these preliminary assays do not provide conclusive evidence that such an interaction will lead to a significant biological change (Ref. 103). Conversely, lack of binding does not rule out an effect (*e.g.,* compounds could affect synthesis or metabolism of a hormone, resulting in drug-induced changes in hormone levels indirectly).

a. *Traditional studies.* General nonclinical toxicity and reproductive/developmental studies such as the ones described in this section are generally sufficient to identify potential hormonal effects on the developing offspring. Developmental and reproductive toxicity caused by hormonal effects will generally be identified using these traditional studies if the tested active ingredient induces a detectable change in the hormone-responsive tissues typically evaluated in the traditional toxicity study designs.

*Repeat-dose toxicity (RDT) studies.* RDT studies typically include a variety of endpoints, such as changes in body weight gain, changes in organ weights, gross organ changes, clinical chemistry changes, or histopathology changes, which can help identify adverse hormonal effects of the tested drug. Also, the battery of organs typically collected for histopathological evaluation in RDT studies includes reproductive organs and the thyroid gland, which can indicate potential adverse hormonal effects. For example, estrogenic compounds can produce effects such as increased ovarian weight and stimulation, increased uterine weight and endometrial stimulation, mammary gland stimulation, decreased thymus weight and involution, or increased bone mineral density.

*DART studies.* Some developmental stages that are evaluated in DART studies, such as the gestational and neonatal stages, may be particularly sensitive to hormonally active compounds. Note, however, that traditional DART studies capture gestational developmental time points effectively, but are less adequate for evaluation of effects on postnatal development. Endpoints in pre/postnatal DART studies that may be particularly suited for detecting hormonal effects include vaginal patency, preputial separation,

anogenital distance, and nipple retention. Behavioral assessments (*e.g.,* mating behavior) of offspring may also detect neuroendocrine effects.

*Carcinogenicity studies.* A variety of tumors that result from long-term hormonal disturbance can be detected in carcinogenicity assays. For example, the effect of a persistent disturbance of particular endocrine gland systems (*e.g.,* hypothalamic-pituitary-adrenal axis) can be detected in these bioassays. Certain hormone-dependent ovarian and testicular tumors and parathyroid hormone-dependent osteosarcoma also can be detected in rodent carcinogenicity bioassays.

b. *Supplementary studies.* If no signals are obtained in the traditional RDT, DART, and carcinogenicity studies, assuming the studies covered all the life stages at which a health care antiseptic user may be exposed to such products (*e.g.,* pregnancy, infancy, adolescence), then no further assessment of drug-induced hormonal effects are needed. However, if a positive response is seen in any of these animal studies and this response is not adequately understood, then additional studies, such as mechanistic studies involving alternative animal models, may be needed (Refs. 98, 104, 105, and 106). For example, juvenile animal studies can help address the long-term hormonal effects from acute or continuous exposure to drugs that are administered to neonates and children, when these effects cannot be adequately predicted from existing data. As an alternative to, or in addition to, supplemental nonclinical assessment of hormonal effects, inclusion of endocrine endpoints (*e.g.,* hormone levels) in clinical studies can be important to clarify the relevance of adverse hormonal effects identified in nonclinical studies.

*Juvenile animal studies.* Young animals are considered juveniles after they have been weaned. In traditional DART studies, neonatal animals (pups) are typically dosed only until they are weaned. If a drug is not secreted via the mother's milk, the DART study will not be able to test the direct effect of the drug on the pup. Furthermore, since pups are not dosed after weaning, they are not exposed to the drug during the juvenile stage of development. A juvenile animal toxicity study in which the young animals are dosed directly can be used to evaluate potential drug-induced effects on postnatal development for products intended for pediatric populations.

*Pubertal animal studies.* The period between the pup phase and the adult phase, referred to as the juvenile phase of development, includes the pubertal period in which the animal reaches puberty and undergoes important growth landmarks. In mammals, puberty is a period of rapid morphological changes and endocrine activity. Studies in pubertal animals are designed to detect alterations of pubertal development, thyroid function, and hypothalamic-pituitary-gonadal system maturation (Ref. 107).

In those cases where adverse effects are noted on the developing offspring, FDA intends to conduct a risk-benefit analysis based on the dose-response observed for the findings and the animal-to-human exposure comparison. If such an assessment indicates a potential risk to humans, then we will include that risk in our risk-benefit analysis in order to determine whether the antiseptic active ingredient at issue is suitable for inclusion in an OTC monograph.

4. Studies To Evaluate the Potential Impact of Antiseptic Active Ingredients on the Development of Resistance

Since the 1994 TFM published, the issue of antiseptic resistance and whether bacteria that exhibit antiseptic resistance have the potential for antibiotic cross-resistance has been the subject of much study and scrutiny. One of the major mechanisms of antiseptic and antibiotic cross-resistance is changes in bacterial efflux activity at nonlethal concentrations of the antiseptic (Refs. 66, 69, 76, 108, 109, and 110). Efflux pumps are an important nonspecific bacterial defense mechanism that can confer resistance to a number of substances toxic to the cell, including antibiotics (Refs. 111 and 112). The development of bacteria that are resistant to antibiotics is an important public health issue, and additional data may tell us whether use of antiseptics in health care settings may contribute to the selection of bacteria that are less susceptible to both antiseptics and antibiotics. Therefore, we are requesting additional data and information to address this issue.

Laboratory studies are a feasible first step in evaluating the impact of exposure to nonlethal amounts of antiseptic active ingredients on antiseptic and antibiotic bacterial susceptibilities. As discussed in section VII.D, some of the active ingredients evaluated in this proposed rule have laboratory data demonstrating that bacteria have developed reduced susceptibility to antiseptic active ingredients and antibiotics after exposure to nonlethal concentrations of the antiseptic active ingredient. However, only limited data exist on the effects of antiseptic exposure on the bacteria that are predominant in the oral cavity, gut, skin flora, and the environment (Ref. 113). These organisms represent pools of resistance determinants that are potentially transferable to human pathogens (Refs. 114 and 115). Broader laboratory testing of each health care antiseptic active ingredient would more clearly define the scope of the impact of antiseptic active ingredients on the development of antibiotic resistance and provide a useful preliminary assessment of an antiseptic active ingredient's potential to foster the development of resistance.

Studies evaluating the impact of antiseptic active ingredients on the antiseptic and antibiotic susceptibilities of each of the following types of organisms could help support a GRAS determination for antiseptic active ingredients intended for use in OTC health care antiseptic drug products:

- Human bacterial pathogens;
- nonpathogenic organisms, opportunistic pathogens, and obligate anaerobic bacteria that make up the resident microflora of the human skin, gut, and oral cavity; and
- nonpathogenic organisms and opportunistic pathogens from relevant environmental sources (*e.g.,* patient rooms, surgical suites).

If the results of these studies show no evidence of changes in antiseptic or antibiotic susceptibility, then we propose that no further studies addressing the development of resistance are needed to support a GRAS determination.

However, for antiseptic active ingredients that demonstrate an effect on antiseptic and antibiotic susceptibilities, additional data will be necessary to help assess the likelihood that changes in susceptibility observed in the preliminary studies would occur in the health care setting. Different types of data could be used to assess whether or not ingredients with positive laboratory findings pose a public health risk (Ref. 291). We do not anticipate that it will be necessary to obtain data from multiple types of studies for each active ingredient to adequately assess its potential to affect resistance. Such types of data could include, but are not limited to, the following:

- Information about the mechanism(s) of antiseptic action (for example, membrane destabilization or inhibition of fatty acid synthesis), and whether there is a change in the mechanism of action with changes in antiseptic concentration;
- information clarifying the bacteria's mechanism(s) for the development of

resistance or reduced susceptibility to the antiseptic active ingredient (for example, efflux mechanisms);

- data characterizing the potential for reduced antiseptic susceptibility caused by the antiseptic active ingredient to be transferred to other bacteria that are still sensitive to the antiseptic;
- data characterizing the concentrations and antimicrobial activity of the antiseptic active ingredient in biological and environmental compartments (for example, on the skin, in the gut, and in environmental matrices); and
- data characterizing the antiseptic and antibiotic susceptibility levels of environmental isolates of bacteria in areas of prevalent health care antiseptic use (for example, patient rooms and surgical suites).

These data can help ascertain whether or not a health care antiseptic active ingredient is likely to induce nonspecific bacterial resistance mechanisms. These data could also help determine the likelihood that changes in susceptibility would spread to other bacterial populations and whether or not concentrations of health care antiseptics exist in relevant biological and environmental compartments that are sufficient to induce changes in bacterial susceptibilities. Data on the antiseptic and antibiotic susceptibilities of bacteria in areas of prevalent health care antiseptic use can help demonstrate whether or not changes in susceptibility are occurring with actual use. Because actual use concentrations of health care antiseptics are much higher than the MICs for these active ingredients, data from compartments where sublethal concentrations of biologically active antiseptic active ingredients may occur (*e.g.,* environmental compartments) can give us a sense of the potential for change in antimicrobial susceptibilities in these compartments (Refs. 116, 117, and 118). FDA recognizes, however, that methods of evaluating this issue are an evolving science and that there may be other data appropriate to evaluate the impact of health care antiseptic active ingredients on the development of resistance. For this reason, FDA encourages interested parties to consult with the Agency on the specific studies appropriate to address this issue for a particular active ingredient.

*D. Review of Available Data for Each Antiseptic Active Ingredient*

We have identified for each health care antiseptic active ingredient whether the studies outlined in section VII.C are publicly available. Table 10 lists the types of studies available for each antiseptic active ingredient proposed as Category I or Category III in the 1994 TFM and indicates whether the currently available data are adequate to serve as the basis of a GRAS determination. Although we have some data from submissions to the rulemaking and from information we have identified in the literature, our administrative record is incomplete for at least some types of safety studies for each of the active ingredients (see table 10). As noted previously in this document, only information that is part of the administrative record for this rulemaking can form the basis of a GRAS/GRAE determination.

We recognize that data and information submitted in response to the 2013 Consumer Wash PR may be relevant to this proposed rule for those active ingredients eligible for use as both consumer and health care antiseptics. At the time of publication of this proposed rule, FDA's review of all submissions made to the 2013 Consumer Wash PR had not been completed. To be considered in this rulemaking, any information relevant to health care antiseptic active ingredients must be resubmitted under this docket (FDA–2015–N–0101) for consideration.

TABLE 10—SAFETY STUDIES AVAILABLE FOR HEALTH CARE ANTISEPTIC ACTIVE INGREDIENTS [1]

| Active ingredient [2] | Human pharmacokinetic (MUsT) | Animal pharmacokinetic (ADME) | Oral carcinogenicity | Dermal carcinogenicity | Reproductive toxicity (DART) | Potential hormonal effects | Resistance potential |
|---|---|---|---|---|---|---|---|
| Alcohol | ○ | • | • | • | • | • | • |
| Benzalkonium chloride | | | ○ | | | | ○ |
| Benzethonium chloride | | ○ | | • | ○ | | ○ |
| Chloroxylenol | ○ | ○ | | | ○ | | ○ |
| Hexylresorcinol | | ○ | • | | | | |
| **Simple iodine solutions** | | | | | | | |
| Iodine tincture USP | ○ | • | [3] • | | [3] • | • | |
| Iodine topical solution USP | ○ | • | [3] • | | [3] • | • | |
| **Iodine complexes** | | | | | | | |
| Povidone-iodine | [4] ○ | [5] • | [3] • | | [3] • | • | |
| Isopropyl alcohol | ○ | ○ | | ○ | • | ○ | • |
| Triclocarban | ○ | ○ | • | | ○ | ○ | |
| Triclosan | [4] ○ | ○ | • | | • | ○ | ○ |

[1] Empty cell indicates no data available; "○" indicates incomplete data available; "•" indicates available data are sufficient to make a GRAS/GRAE determination.

[2] The following active ingredients are not included in the table because no safety data were submitted or identified since the 1994 TFM: Cloflucarban; combination of calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative; combination of mercufenol chloride and secondary amyltricresols in 50 percent alcohol; fluorosalan; iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate); iodine complex (phosphate ester of alkylaryloxy polyethylene glycol); mercufenol chloride; methylbenzethonium chloride; nonylphenoxypoly (ethyleneoxy) ethanoliodine; phenol (less than 1.5 percent); phenol (greater than 1.5 percent); poloxamer-iodine complex; secondary amyltricresols; sodium oxychlorosene; triple dye; and undecoylium chloride iodine complex.

[3] Based on studies of potassium iodide.

[4] The change in classification from sufficient data to incomplete data compared to the Consumer Wash PR (78 FR 76444 at 76458) is a reflection of the higher frequency of use in the health care setting.

[5] Applies to povidone molecules greater than 35,000 daltons.

In the remainder of this section, we discuss the existing data and data gaps for each of the following health care antiseptic active ingredients that was proposed as GRAS in the 1994 TFM and explain why these active ingredients are

no longer proposed as GRAS for use in health care antiseptics (*i.e.,* why they are now proposed as Category III):

- Alcohol
- Hexylresorcinol
- Iodine tincture USP
- Iodine topical solution USP
- Isopropyl alcohol
- Povidone-iodine
- Triclocarban

We also discuss the following antiseptic active ingredients that were proposed as Category III in the 1994 TFM and for which there are some new data available and explain why these ingredients are still Category III:

- Benzalkonium chloride
- Benzethonium chloride
- Chloroxylenol
- Triclosan

We do not discuss the following antiseptic active ingredients that were proposed as Category III in the 1994 TFM because we are not aware of any new safety data for these active ingredients:

- Cloflucarban
- Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
- Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
- Mercufenol chloride
- Mercufenol chloride and secondary amyltricresols in 50 percent alcohol
- Methylbenzethonium chloride
- Nonylphenoxypoly (ethyleneoxy) ethanoliodine
- Phenol (less than 1.5 percent)
- Poloxamer-iodine complex
- Secondary amyltricresols
- Sodium oxychlorosene
- Undecoylium chloride iodine complex

1. Alcohol

In the 1994 TFM, FDA proposed to classify alcohol as GRAS for all health care antiseptic uses based on the recommendation of the Miscellaneous External Panel, which concluded that the topical application of alcohol is safe (47 FR 22324 at 22329 and 59 FR 31402 at 31412). FDA is now proposing to classify alcohol as Category III. Extensive studies have been conducted to characterize the metabolic and toxic effect of alcohol in animal models. Although the impetus for most of the studies has been to study the effects of alcohol exposure via the oral route of administration, some dermal toxicity studies are available and have shown that, although there is alcohol absorption through human skin, it is much lower than absorption via the oral route. Overall, there are adequate safety data to make a GRAS determination for alcohol, with the exception of human pharmacokinetic data under maximal use conditions.

a. Summary of Alcohol Safety Data

*Alcohol human pharmacokinetic data.* Some published data are available to characterize the level of dermal absorption and expected systemic exposure in adults as a result of topical use of alcohol-containing health care antiseptics. As shown in table 11, a variety of alcohol-based hand rub product formulations and alcohol concentrations have been used in these studies. Based on the available data, which represents moderate hand rub use (7.5 to 40 hand rub applications per hour, studied for 30 to 240 minutes), the highest observed exposure was 1,500 milligrams (mg) of alcohol (Ref. 4), which is the equivalent of 10 percent of an alcohol-containing drink.[5] (See also the discussion of occupational exposure to alcohol via the dermal route (Ref. 119) in the alcohol carcinogenicity section of this proposed rule.) Although the available data suggest that dermal absorption of alcohol as a result of health care antiseptic use is relatively low, these studies do not reflect the amount of exposure that may occur during a regular 8- to 12-hour work shift in a health care facility. Consequently, human pharmacokinetics data under maximal use conditions as determined by a MUsT are still needed to make a GRAS determination.

TABLE 11—RESULTS OF ALCOHOL HAND RUB ABSORPTION STUDIES IN HUMANS

| Study | Number of subjects | Amount of alcohol in hand rub (percent) | Volume of hand rub used (milliliter (mL)) | Number of hand rub applications during the study | Total length of assessment | Highest blood alcohol level detected (Milligram/Deciliter (mg/dL)) |
|---|---|---|---|---|---|---|
| Kramer, et al. (Ref. 4) | 12 | 95 | 4 | 20 | 30 minutes | 2.10 |
| Kramer, et al. (Ref. 4) | 12 | 95 | [1] 4 | 10 | 80 minutes | 1.75 |
| Kramer, et al. (Ref. 4) | 12 | 85 | 4 | 20 | 30 minutes | 1.15 |
| Kramer, et al. (Ref. 4) | 12 | 85 | [1] 4 | 10 | 80 minutes | 3.01 |
| Kirschner, et al. (Ref. 120) | 14 | 74.1 | [2] 20 | One 10-minute application. | 10 minutes | ~0.175 |
| Brown, et al. (Ref. 121) | 20 | 70 | 1.2–1.5 | 30 | 1 hour | 1.2 |
| Ahmed-Lecheheb, et al. (Ref. 122) | 86 | 70 | 3 | Average of 9 [3]. | 4 hours | 0.022 |
| Miller, et al. (Ref. 5) | 5 | 62 | 5 | 50 | 4 hours | < 5 |
| Miller, et al. (Ref. 123) | 1 | 62 | 5 | 25 | 2 hours | < 5 |
| Kramer, et al. (Ref. 4) | 12 | 55 | 4 | 20 | 30 minutes | 0.69 |
| Kramer, et al. (Ref. 4) | 12 | 55 | [1] 4 | 10 | 80 minutes | 0.88 |
| Bessonneau, V. and O. Thomas (Ref. 124). | 1 | 70 | 3 | 5 | NA [4] | 1.43 [5] |
| Bessonneau, V. and O. Thomas (Ref. 124). | 1 | 70 | [1] 3 mL x 2 | 5 | NA | 2.02 [5] |

[1] Product applied using a surgical scrub procedure.
[2] Product applied to the subject's back rather than to the hands to exclude any significant interference of inhaled uptake of evaporated alcohol.
[3] Assessed under actual use conditions in a hospital.
[4] Not available because of different study design.
[5] Alcohol concentration measured in air collected from the subject's breathing zone.

[5] One alcohol-containing drink is equivalent to approximately 14 grams of alcohol (Ref. 290).

*Alcohol ADME data.* Animal absorption studies have been conducted both in vitro (Ref. 125) and in vivo in several species (Refs. 126 through 129). After absorption, alcohol is metabolized primarily in the liver by alcohol dehydrogenase to acetaldehyde. Acetaldehyde, in turn, is rapidly metabolized to acetic acid by aldehyde dehydrogenase. These data are sufficient to show that about 5 percent of consumed alcohol is excreted in breath and another 5 percent in urine, with negligible amounts excreted in sweat and feces. Overall, the available animal ADME data are adequate to make a GRAS determination.

*Alcohol carcinogenicity data.* The carcinogenicity of alcohol has been studied by both the dermal and oral routes of administration in animals and by the oral route of administration in humans. These studies are sufficient to characterize the risk of carcinogenesis from the use of alcohol-containing health care antiseptics. Based on two adequate and well-controlled trials, chronic dermal application of alcohol does not appear to be carcinogenic in animals and no further dermal carcinogenicity data are needed to make a GRAS determination (Refs. 130 and 131).

Dermal carcinogenicity data have been obtained from studies where alcohol was used as a vehicle control in 2-year studies. For example, a study performed by the National Toxicology Program (NTP) evaluated the carcinogenic potential of diethanolamine by the dermal route of administration in rats and mice (Ref. 130). Each species had a vehicle control group that was treated with alcohol only. The skin of F334/N rats (50/sex/group) and B6C3F1 mice (50/sex/group) was treated with 95 percent alcohol for 5 days per week for 103 weeks. The amount of alcohol administered corresponds to a daily dose of 442 mg/kilogram(kg)/day and 1,351 mg/kg/day in rats and mice, respectively. None of the alcohol-treated rats or mice showed any skin tumors; however, every mouse group, including the alcohol-alone treatment, showed high incidences of liver tumors. It is unclear whether the high liver tumor incidence was caused by background incidence or by the chronic topical application of alcohol. Dermal administration of alcohol to the skin did not result in skin tumors under the conditions of this study.

Another study performed by the NTP evaluated the carcinogenic potential of benzethonium chloride by the dermal route of administration in rats and mice (Ref. 131). Each species had a vehicle control group that was treated with 95 percent alcohol only. The rats and mice were treated for 5 days per week for 103 weeks. There was no evidence of an increased incidence of skin tumors in the alcohol-treated rats or mice.

In another study, alcohol was used as a vehicle control in the dermal administration of 9,10-dimethyl-1,2-benzanthracene (DMBA), a known carcinogen (Ref. 132). Application of 0.02 mL alcohol alone on the skin of mice 3 times per week for 20 weeks did not cause any tumors. Despite the fact that this study did not cover the entire lifespan of the mice, it provides additional support that alcohol is not tumorigenic to skin after prolonged dermal administration.

In contrast, chronic administration of orally ingested alcohol has been associated with carcinogenicity in both animals and humans (Ref. 133). In animals, alcohol treatment increased tumor incidences in multiple organs (Refs. 134, 135, and 136). In humans, drinking around 50,000 mg of alcohol per day increases the risk for cancers of the oral cavity, pharynx, larynx, esophagus, liver, colon, and rectum in both men and women, and breast cancer in women (Refs. 119 and 137). However, no significant increases in cancer risk for any of these types of cancer appear to be associated with less than one alcoholic drink (about 14,000 mg of alcohol) per day. Based on currently available human absorption data, the highest observed alcohol exposure was 1,500 mg after use equivalent to 40 rubs per hour (Ref. 4), which is far below the alcohol levels that have been shown to be associated with cancer.

Bevan and colleagues evaluated the potential cancer risk from occupational exposures to alcohol via the inhalation and dermal routes, including the risk to health care workers (Ref. 119). They estimated that under a ''worst-case scenario'' of a hospital worker disinfecting both hands and lower arms with alcohol 20 times per day, dermal uptake would be approximately 600 mg alcohol/day. When a more realistic worst-case estimate of 100 hand rubs per day is used (Ref. 101), systemic alcohol exposure may be as high as 6,825 mg/day, assuming bioavailability remains at 2.3 percent for 95 percent alcohol (Ref. 4). Ultimately, systemic exposure data from a human MUsT are needed to fully assess the risk to health care workers.

*Alcohol DART data.* The developmental and reproductive toxicity profile of orally administered alcohol is well characterized. In many animal species, exposure to alcohol during pregnancy can result in retarded development and structural malformations of the fetus. In humans, consumption of even small amounts of alcohol in pregnant women may result in fetal alcohol spectrum disorders (FASD) and other major structural malformations; therefore, according to the Centers for Disease Control and Prevention, there is no known level of safe alcohol consumption during pregnancy (Ref. 138). The most severe form of FASD, fetal alcohol syndrome, has been documented in infants of mothers who consumed large amounts of alcohol throughout pregnancy (Ref. 292). Based on available absorption data, however, it is highly unlikely that the levels of alcohol absorbed as a result of health care antiseptic use would approach the levels that cause fetal alcohol syndrome.

*Alcohol data on hormonal effects in animals.* Alcohol exposure affects the level of a number of different hormones in animals. In vitro studies have shown that alcohol at a concentration of 280 to 300 mg/dL increased production of human chorionic gonadotropin and progesterone by cultured trophoblasts (Ref. 139), and at concentrations of at least 2,500 mg/dL, decreased the ability of rat Leydig cells to secrete testosterone by up to 44 percent (Ref. 140). There are also many in vivo studies of the effects of alcohol on hormone levels in animals after oral administration. Alcohol exposures are associated with suppression of the hypothalamic pituitary gonadal (HPA) axis in male rats. For example, in an alcohol feeding study where adult rats were treated for 5 weeks with 6 percent alcohol, resulting in blood alcohol levels of 110 to 160 mg/dL, the serum and testicular testosterone concentrations of the alcohol group were significantly lower than in untreated controls ($P < 0.01$) (Ref. 141). The serum luteinizing hormone concentration of alcohol-treated rats was significantly higher than that of diet controls ($P < 0.01$), but the pituitary luteinizing hormone, the serum and pituitary follicle-stimulating hormone, and the prolactin concentrations did not differ. When the effect of alcohol exposure was compared in prepubescent and adult rats, treatment with 500 to 4,000 mg alcohol/kg decreased serum testosterone levels in adult rats as expected (Ref. 293). In contrast, the opposite effect was observed in prepubescent male rats (25–30 days old) where alcohol treatment produced dose-dependent increases in serum testosterone levels. Serum luteinizing hormone levels in alcohol-treated rats were either unchanged or only modestly decreased in all ages tested. Results of this study suggest that

alcohol at serum levels of greater than 200 mg/dL exerts age-dependent effects on the synthesis and secretion of testosterone throughout sexual maturation in rats. Overall, the effects of alcohol on hormones in animals have been well characterized and no additional data are needed to make a GRAS determination.

*Alcohol data on hormonal effects in humans.* The effects of alcohol on human hormones are multiple and complex. Several variables, including the type, length, and pattern of alcohol exposure, and coexisting medical problems, such as malnutrition and liver dysfunction, must be considered when assessing the impact of alcohol on hormonal status (Ref. 142). Pregnant health care workers are a potentially vulnerable population given that alcohol is a teratogen, and alcohol-containing antiseptic hand rubs are used frequently in health care settings. Alcohol in the maternal bloodstream crosses readily into the placenta and the fetal compartment (Ref. 143). This results in similar blood alcohol concentrations in the mother, the fetus, and the amniotic fluid (Ref. 143). The fetus has very limited metabolic capacity for alcohol primarily because of low to absent hepatic activity for the metabolism of alcohol (Ref. 144). Although both the placenta and fetus have some capacity to metabolize alcohol, the majority of alcohol metabolism occurs in maternal metabolic systems outside of the fetal compartment (Ref. 143).

Maternal alcohol use (by ingestion) is the leading known cause of developmental and cognitive disabilities in the offspring, and is a preventable cause of birth defects (Ref. 145). However, based on available absorption data, it is highly unlikely that the levels of alcohol absorbed as a result of health care antiseptic use would approach the levels that cause fetal alcohol syndrome. Nonetheless, children exposed to lower levels of alcohol in utero may be vulnerable to more subtle effects. Currently, the levels of alcohol exposure that cause more subtle effects are unknown.

Unlike the abundance of data from oral exposure, there are no data on the effects of systemic exposure to alcohol during pregnancy from the use of alcohol-containing hand rubs. There are, however, some pharmacokinetic data on alcohol absorption after hand rub use in the nonpregnant population (described in the human pharmacokinetic subsection of this section of the proposed rule). As noted previously, the available data suggest that with moderate health care antiseptic hand rub use (*e.g.,* evaluations of the amount of alcohol in the blood at up to 4 hours of use), systemic alcohol exposure is relatively low, but may be as high as 10 percent of an alcohol-containing drink. However, health care workers who use these products chronically and repetitively may be required to use alcohol-containing hand rubs in situations such as prior to and following contact with patients or contact with body fluids, and therefore may be exposed to these products a hundred times or more per day (Ref. 101). Consequently, additional human pharmacokinetic data are needed to determine the level of alcohol exposure following maximal use of health care antiseptics (*i.e.,* MUsT) to determine the level of risk from the use of these products.

*Alcohol resistance data.* The antimicrobial mechanism of action of alcohol is considered nonspecific. It is believed that alcohol has multiple toxic effects on the structure and metabolism of microorganisms, primarily caused by denaturation and coagulation of proteins (Refs. 146 through 149). Alcohol's reactive hydroxyl (-OH) group readily forms hydrogen bonds with proteins, which leads to loss of structure and function, causing protein and other macromolecules to precipitate (Ref. 148). Alcohol also lyses the bacterial cytoplasmic membrane, which releases the cellular contents and leads to bacterial inactivation (Ref. 146). Because of alcohol's speed of action and multiple, nonspecific toxic effects, microorganisms have a difficult time developing resistance to alcohol. Of note, researchers have been attempting to develop alcohol-tolerant bacteria for use in biofuel production and beverage biotechnology applications. One of the most alcohol-tolerant bacteria, *Lactobacillus,* has been shown to grow in the presence of up to 13 percent alcohol, which is far lower than the alcohol concentrations present in health care antiseptic products (Ref. 150). Health care antiseptic products contain at least 60 percent alcohol (59 FR 31402 at 31442), and bacteria are unable to grow in this relatively high concentration of alcohol. Furthermore, alcohol evaporates readily after topical application, so no significant antiseptic residue is left on the skin that could contribute to the development of resistance (Refs. 146 and 148). Consequently, the development of resistance as a result of health care antiseptic use is unlikely, and additional data on the development of antimicrobial resistance to alcohol are not needed to support a GRAS determination.

b. *Alcohol safety data gaps.* In summary, our administrative record for the safety of alcohol is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure alcohol and its metabolites and
- data to help define the effect of formulation on dermal absorption.

2. Benzalkonium Chloride

In the 1994 TFM, FDA categorized benzalkonium chloride in Category III because of a lack of adequate safety data for its use as both a health care personnel hand wash and surgical hand scrub (59 FR 31402 at 31435). FDA continues to propose benzalkonium chloride as Category III. Because of its widespread use as an antimicrobial agent in cosmetics and as a disinfectant for hard surfaces in agriculture and medical settings, the safety of benzalkonium chloride has also been reviewed by the Environmental Protection Agency and an industry review panel (Cosmetic Ingredient Review (CIR)) (Refs. 151 and 152) and found to be safe for disinfectant and cosmetic uses, respectively. Both these evaluations have been cited by the comments in support of the safety of benzalkonium chloride as a health care antiseptic wash active ingredient (Ref. 153).

Each of these evaluations cites findings from the type of studies necessary to support the safety of benzalkonium chloride for repeated daily use. However, the data that are the basis of these safety assessments are proprietary and are publicly available only in the form of summaries. Consequently, these studies are not available to FDA and are precluded from a complete evaluation by FDA. In addition, the submitted safety assessments with study summaries do not constitute an adequate record on which to base a GRAS classification (see generally § 330.10(a)(4)(i)). For FDA to evaluate the safety of benzalkonium chloride for this rulemaking, these studies must be submitted to the rulemaking or otherwise be made publicly available.

In addition to these summaries, as discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76463), FDA has reviewed studies on resistance data and antibiotic susceptibility of certain bacteria (Refs. 62, 68, 70, 71, 73, 154, 155, and 156), and determined that the available studies have examined few

bacterial species, provide no information on exposure levels, and are not adequate to define the potential for the development of resistance or cross-resistance. Additional data are needed to more clearly define the potential for the development of resistance to benzalkonium chloride. Also, currently, no oral or dermal carcinogenicity data are publicly available. Thus, additional safety data are needed before benzalkonium chloride can be confirmed to be GRAS for use in health care antiseptic products.

*Benzalkonium chloride safety data gaps.* In summary, our administrative record for the safety of benzalkonium chloride is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure benzalkonium chloride and its metabolites;
- aata to help define the effect of formulation on dermal absorption;
- animal ADME;
- oral carcinogenicity;
- dermal carcinogenicity;
- DART studies;
- potential hormonal effects; and
- data from laboratory studies that assess the potential for the development of resistance to benzalkonium chloride and cross-resistance to antibiotics as discussed in section VII.C.4.

3. Benzethonium Chloride

In the 1994 TFM, FDA classified benzethonium chloride as lacking sufficient evidence of safety for use as a health care personnel hand wash and surgical hand scrub (59 FR 31402 at 31435). FDA is now proposing to classify benzethonium chloride as Category III for both safety and effectiveness. Since publication of the 1994 TFM, two industry review panels (CIR and a second industry panel identified in a comment only as an ''industry expert panel'') and a European regulatory advisory board (Scientific Committee on Cosmetic Products and Non-food Products Intended for Consumers) have evaluated the safety of benzethonium chloride when used as a preservative in cosmetic preparations and as an active ingredient in consumer hand soaps (Refs. 157, 158, and 159). These advisory bodies found benzethonium chloride to be safe for these uses. However, all these safety determinations have largely relied on the findings of proprietary studies that are not publicly available. One of these evaluations, by the unidentified industry expert panel, was submitted to the rulemaking to support the safety of benzethonium chloride (Ref. 160).

Some of the safety data reviewed by the unidentified industry expert panel represent the type of data that are needed to evaluate the safety of benzethonium chloride for use in consumer antiseptic wash products, *e.g.,* ADME, DART, and oral carcinogenicity studies. The safety assessments used to support the unidentified industry expert panel's finding of safety, however, are publicly available only in the form of summaries. Consequently, these studies are not available to FDA for a complete evaluation. Furthermore, the submitted safety assessments with study summaries do not constitute an adequate record on which to base a GRAS classification (see generally § 330.10(a)(4)(i)). For FDA to include these studies in the administrative record for this rulemaking, the studies must be submitted to the rulemaking or otherwise made publicly available.

In addition to these summaries, as discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76464–76465), FDA has reviewed the following: (1) ADME studies providing data from dermal and intravenous administration to rats and a rat in vitro dermal absorption study (Refs. 131 and 160 through 163). FDA determined that additional data from ADME studies in animals are necessary to support a GRAS determination because of highly variable results in the submitted studies, the need to clearly define the level of dermal absorption, the effect of formulation on dermal absorption, and the distribution and metabolism of benzethonium chloride in animals; (2) A dermal carcinogenicity study (Ref. 131), which is adequate to show that benzethonium chloride does not pose a risk of cancer after repeated dermal administration; however, oral carcinogenicity data are still lacking; (3) DART data from teratology studies on rats and rabbits, as well as an embryo-fetal rat study (Ref. 160) and determined that the DART data are not adequate to characterize all aspects of reproductive toxicity and that studies are needed to assess the effect of benzethonium chloride on male and female fertility and on prenatal and postnatal endpoints; and (4) Resistance data from studies on bacterial susceptibility for benzethonium chloride and antibiotics (Refs. 164 and 165) and determined that the available studies examine few bacterial species, provide no information on the level of benzethonium chloride exposure, and are not adequate to define the potential for the development of resistance and cross-resistance to antibiotics.

Additional laboratory studies are necessary to more clearly define the potential for the development of resistance to benzethonium chloride. In addition, we lack human pharmacokinetic studies under maximal use conditions, which are needed to define the level of systemic exposure following repeated use. Thus, additional safety data are needed before benzethonium chloride can be confirmed to be GRAS for use in health care antiseptic products.

*Benzethonium chloride safety data gaps.* In summary, our administrative record for the safety of benzethonium chloride is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure benzethonium chloride and its metabolites;
- data to help define the effect of formulation on dermal absorption;
- animal ADME;
- oral carcinogenicity;
- DART studies (fertility and embryo-fetal testing);
- potential hormonal effects; and
- data from laboratory studies that assess the potential for the development of resistance to benzethonium chloride and cross-resistance to antibiotics as discussed in section VII.C.4.

4. Chloroxylenol

In the 1994 TFM, FDA classified chloroxylenol as lacking sufficient evidence of safety for use as a health care personnel hand wash and surgical hand scrub for FDA to determine whether chloroxylenol is GRAS for use in health care antiseptic products (59 FR 31402 at 31435). FDA is now proposing to classify chloroxylenol as Category III for both safety and effectiveness. Additional safety data continue to be needed to support the long-term use of chloroxylenol in OTC health care antiseptic products. As discussed in the 2013 Consumer Wash PR, chloroxylenol is absorbed after topical application in both humans and animals. However, studies conducted in humans and animals are inadequate to fully characterize the extent of systemic absorption after repeated topical use or to demonstrate the effect of formulation on dermal absorption. The administrative record also lacks other important data to support a GRAS determination for this antiseptic active ingredient.

As discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76465–76467), FDA reviewed the following:

• Human pharmacokinetic data from dermal and percutaneous absorption studies (Refs. 166 and 167) and determined that the human pharmacokinetic studies are inadequate and studies using dermal administration under maximal use conditions are needed to define the level of systemic exposure following repeated use and the effect of formulation on dermal absorption;

• dermal ADME studies (Refs. 168 and 169) that demonstrated that absorption of chloroxylenol occurs after dermal application in humans and animals, but that the administrative record for chloroxylenol still lacks data to fully characterize the rate and extent of systemic absorption, the similarities and differences between animal and human metabolism of chloroxylenol under maximal use conditions, and data to help establish the relevance of findings observed in animal toxicity studies to humans;

• carcinogenicity data from a dermal toxicity study in mice (Ref. 170) and determined that a long-term dermal carcinogenicity study and an oral carcinogenicity study are needed to characterize the systemic effects from long-term exposure;

• DART data from a teratolotgy study in rats (Ref. 171) and determined that additional studies are necessary to assess the effect of chloroxylenol on fertility and early embryonic development and on prenatal and postnatal development; and

• resistance data from studies on antibiotic susceptibility in chloroxylenol-tolerant bacteria and antimicrobial susceptibilities of bacteria from industrial sources (Refs. 156, 164, 171, and 172) and determined that these studies examine few bacterial species, provide no information on the level of chloroxylenol exposure, and are not adequate to define the potential for the development of resistance to chloroxylenol and cross-resistance to antibiotics.

Thus, additional safety data are needed before chloroxylenol can be confirmed to be GRAS for use in health care antiseptic products.

*Chloroxylenol safety data gaps.* In summary, our administrative record for the safety of chloroxylenol is incomplete with respect to the following:

• Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure chloroxylenol and its metabolites;

• data to help define the effect of formulation on dermal absorption;

• animal ADME at toxic exposure levels;

• dermal carcinogenicity;

• oral carcinogenicity;

• DART studies defining the effects of chloroxylenol on fertility and prenatal and postnatal development;

• potential hormonal effects; and

• data from laboratory studies that assess the potential for the development of resistance to chloroxylenol and cross-resistance to antibiotics as discussed in section VII.C.4.

5. Hexylresorcinol

In the 1994 TFM, FDA proposed to classify hexylresorcinol as GRAS for all antiseptic uses covered by that TFM, including health care antiseptic uses, based on the recommendations of the Panel, who concluded that the topical application of hexylresorcinol is safe (39 FR 33103 at 33134). FDA is now proposing to classify hexylresorcinol as Category III. In support of its GRAS conclusion, the Panel cited hexylresorcinol's long history of use as an oral antihelmintic (a drug used in the treatment of parasitic intestinal worms) in humans and the lack of allergic reactions or dermatitis associated with topical use. The Panel noted that no information was provided regarding dermal or ophthalmic toxicity or absorption and blood levels attained after application to intact or abraded skin or mucous membranes, but concluded that the few animal toxicity studies submitted as summaries indicated a ''low order'' of toxicity (Ref. 173).

In light of the new safety information about systemic exposure to antiseptic active ingredients, the data relied on by the Panel should be supplemented to support a GRAS determination. Currently, there are only minimal data available to assess the safety of the repeated, daily, long-term use of hexylresorcinol. As discussed in the proposed rule covering consumer antiseptic washes (78 FR 76444 at 76458), FDA has reviewed an adequate oral carcinogenicity study with results it considers negative (Ref. 174), an ADME study providing data from oral administration to dogs (Ref. 175) and humans (Ref. 176), and other information, and determined that additional safety data are needed before hexylresorcinol can be considered GRAS for use in OTC antiseptic products. We conclude that these data gaps also exist for use as a health care antiseptic.

*Hexylresorcinol safety data gaps.* In summary, our administrative record for the safety of hexylresorcinol is incomplete with respect to the following:

• Human pharmacokinetic studies under maximal use conditions when applied topically (*i.e.,* MUsT), including documentation of validation of the methods used to measure hexylresorcinol and its metabolites;

• data to help define the effect of formulation on dermal absorption;

• animal ADME;

• dermal carcinogenicity;

• DART studies;

• potential hormonal effects; and

• data from laboratory studies that assess the potential for the development of resistance to hexylresorcinol and cross-resistance to antibiotics as discussed in section VII.C.4.

6. Iodine-Containing Ingredients

Elemental iodine, which is the active antimicrobial component of iodine-containing antiseptics, is only slightly soluble in water (Ref. 177). Consequently, iodine is frequently dissolved in an organic solvent (such as a tincture) or complexed with a carrier molecule. Both surfactant (*e.g.,* poloxamer) and nonsurfactant (*e.g.,* povidone) compounds have been complexed with iodine. The carrier molecules increase the solubility and stability of iodine by allowing the active form of iodine to be slowly released over time (Ref. 177). The rate of the release of ''free'' elemental iodine from the complex is a function of the equilibrium constant of the complexing formulation (39 FR 33103 at 33129). In the 1994 TFM, all the iodine-containing active ingredients were proposed as GRAS for OTC health care antiseptic use (59 FR 31402 at 31435). FDA is now proposing to classify all iodine-containing active ingredients as Category III for both safety and effectiveness. Since the publication of the 1994 TFM, we have identified new safety data for the following active ingredients:

• Iodine tincture USP

• Iodine topical solution USP

• Povidone-iodine 5 to 10 percent

Iodine is found naturally in the human body and is essential for normal human body function. In the body, iodine accumulates in the thyroid gland and is a critical component of thyroid hormones. People obtain iodine through their food and water, which are often supplemented with iodine to prevent iodine deficiency. Because people are widely exposed to iodine, it has been the subject of comprehensive toxicological review by public health organizations (Refs. 178 and 179).

Much of the safety data we reviewed pertained to elemental iodine alone.

Consequently, additional data on some of the carrier molecules are needed. In the 1994 TFM, FDA stated that neither the medium nor large molecular weight size povidone molecules (35,000 daltons or greater) presented a safety risk when limited to the topical uses described in the monograph and that larger size povidone-iodine molecules would not be absorbed under the 1994 TFM conditions of use (59 FR 31402 at 31424). We continue to think that data on the larger size molecules are not necessary to support a GRAS determination for iodine-containing ingredients. However, data are lacking on the absorption of smaller molecular weight povidone molecules and for other small molecular weight carriers (less than 500 daltons (Ref. 180)). Human absorption studies following maximal dermal exposure to these carriers can be used to determine the potential for systemic toxicity from the carrier molecule. For carrier molecules that are absorbed following dermal exposure, we propose that the following data are needed to support a GRAS determination: Systemic toxicity of the carrier in animal studies that identify the target organ for toxicity, and characterization of the metabolic fate of the carrier as recommended by the Panel (39 FR 33103 at 33130).

As discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76459–76461), FDA has reviewed the following:

- Human pharmacokinetic data from absorption studies (Refs. 178, 181, 182, and 183) and determined that they do not provide sufficient information to estimate typical amounts of iodine that could be absorbed from health care antiseptic products containing iodine and iodine complexes;
- Iodine ADME data (Refs. 178, 184, and 185), and determined that the distribution, metabolism, and excretion of iodine have been adequately assessed in humans and no further animal ADME data are needed to support a GRAS determination;
- Oral carcinogenicity studies providing data from oral administration to rats and tumor promotion in rats (Refs. 186, 187, and 188) and determined that based upon the available data, oral doses of iodine do not significantly raise the risk of cancer in animals and no further oral carcinogenicity data are needed to make a GRAS determination;
- DART data from studies assessing the effects of iodine on reproduction, embryo-fetal development, lactation, and survival in animals (Refs. 178 and 189 through 195) and determined that the effect of iodine on development and reproductive toxicology are well characterized and additional DART studies are not needed to make a GRAS determination; and
- Iodine data on hormonal effects, including studies of the effect of iodine on the thyroid gland (Refs. 178, 179, 181, 183, 190, 191, 192, and 196 through 206), and determined that, despite limitations in some of the studies, FDA believes there are adequate data regarding the potential of iodine to cause changes in thyroid hormone levels and additional studies are not necessary to make a GRAS determination.

In addition, based on the available data, more information is needed to support the frequent, topical use of iodine-containing health care antiseptics by pregnant and breastfeeding health care personnel. Iodine-containing health care antiseptics, particularly povidone-iodine, are used frequently as surgical hand scrubs. Although the daily exposure from surgical hand scrubs would be much lower than from health care personnel hand washes, because of the potential for absorption of iodine and transient hypothyroidism in newborns (Refs. 191, 192, 199, and 203), chronic use of iodine-containing health care antiseptics by pregnant and breastfeeding health care personnel needs to be evaluated. Consequently, additional human pharmacokinetic data are needed to determine the level of iodine exposure following maximal health care antiseptic use (*i.e.,* MUsT) to determine the potential effects from chronic use of these products.

*Iodine safety data gaps.* In summary, our administrative record for the safety of iodine-containing active ingredients is incomplete with respect to the following:

- Human pharmacokinetic studies of the absorption of iodine under maximal use conditions when applied topically (MUsT) for each of the iodine-containing active ingredients, including documentation of validation of the methods used to measure iodine and its metabolites;
- Human absorption studies of the carrier molecule for small molecular weight povidone molecules (less than 35,000 daltons) and the other small molecular weight carriers (less than 500 daltons);
- Dermal carcinogenicity studies for each of the iodine-containing active ingredients; and
- Data from laboratory studies that assess the potential for the development of resistance to iodine and cross-resistance to antibiotics as discussed in section VII.C.4.

7. Isopropyl Alcohol

In the 1994 TFM, FDA proposed to classify isopropyl alcohol (70 to 91.3 percent) as GRAS for all health care antiseptic uses (59 FR 31402 at 31436). FDA is now proposing to classify isopropyl alcohol as Category III. The GRAS determination in the 1994 TFM was based on the recommendations of the Miscellaneous External Panel, which based its recommendations on human absorption data and blood isopropyl alcohol levels (47 FR 22324 at 22329). There was no comprehensive nonclinical review of the toxicity profile of isopropyl alcohol, nor was there a nonclinical safety evaluation of the topical use of isopropyl alcohol. We believe the existing evaluations need to be supplemented to fully evaluate the safety of isopropyl alcohol.

a. Summary of Isopropyl Alcohol Safety Data

*Isopropyl alcohol human pharmacokinetic data.* Based on a review of published literature, there are some data to characterize the level of dermal absorption and expected systemic exposure in adults following topical use of isopropyl alcohol-containing products. However, these data do not cover maximal use in the health care setting. In a study by Brown, *et al.,* the cutaneous absorption of isopropyl alcohol from a commonly used hand rub solution containing 70 percent isopropyl alcohol was assessed in 19 health care workers ranging in age from 22 to 67 years (Ref. 121). The hand rub solution was administered under ''intensive clinical conditions'' by application of 1.2 to 1.5 mL of the isopropyl alcohol-containing hand rub 30 times during a 1-hour period on 2 separate days separated by a 1-day washout. Serum isopropyl alcohol concentrations at 5 to 7 minutes post-exposure as assessed by gas chromatography (lower limit of quantitation of 2 mg/dL) were not detectable in these subjects following the simulated ''intense clinical conditions.''

Another study examined the pharmacokinetics of alcohol and isopropyl alcohol after separate and combined application in a double-blind, randomized, three-way crossover study (Ref. 120). Results show that all isopropyl alcohol concentrations measured in volunteers treated with 10 percent isopropyl alcohol in aqueous solution and the commercial combination product were below the detection limit of 0.5 mg/L. Another study by Turner and colleagues investigated the amount of isopropyl

alcohol absorbed through the skin in 10 healthy male and female adults following application of 3 mL of an isopropyl alcohol-containing hand rub (56 percent w/w isopropyl alcohol) applied to the hands every 10 minutes over a 4-hour period (Ref. 207). Nine of the 10 subjects exhibited measurable blood isopropyl alcohol concentrations at 5 minutes following final application of the hand rub (limit of detection, 0.5 mg/L). The range of isopropyl alcohol concentrations observed in this study was less than 0.5 mg/L to 1.8 mg/L.

A recent report assessed systemic absorption following the use of a hand rub containing 63.14 percent w/w isopropyl alcohol, using a surgical scrub method on 10 adults (Ref. 208). First, a hygienic hand rub was performed for 30 seconds. Ten minutes later, a 1.5-minute surgical hand rub procedure was performed before each of the three consecutive 90-minute surgical interventions. After application of the hand rub and air-drying, surgical gloves were donned. Samples were collected three times at 90-minute intervals after each surgical procedure and at 60 and 90 minutes after the third surgical procedure. The authors report that the highest median blood level was 2.56 mg/L for isopropyl alcohol.

In summary, dermal absorption of isopropyl alcohol following topical application of antiseptic hand rubs under simulated clinical conditions in adults suggests the systemic exposure to isopropyl alcohol when used as an active ingredient in health care antiseptic products is expected to be low. Clinical effects (mild intoxication) of elevated blood isopropyl alcohol levels occur at concentrations exceeding approximately 50 mg/dL (Ref. 209). The highest blood concentration of isopropyl alcohol observed across studies following various application scenarios with isopropyl alcohol-containing products was less than 2 mg/dL, or 4 percent of the systemic levels associated with acute clinical effects. However, the available studies did not assess the highest potential concentration of isopropyl alcohol (91.3 percent) that may be used in a health care antiseptic (59 FR 31402 at 31436), and these studies do not reflect the amount of exposure that may occur during a regular 8- to 12-hour work shift in a health care facility. Consequently, human pharmacokinetic data under maximal use conditions as determined by a MUsT are still needed to support a GRAS determination for isopropyl alcohol for use in health care antiseptic products.

*Isopropyl alcohol ADME data.* There are few animal studies that examine the absorption of isopropyl alcohol following dermal exposure. The majority of studies used non-dermal routes of exposure (*i.e.,* oral or inhalation) (Refs. 210 and 211). The available dermal exposure studies have demonstrated that there is some systemic exposure to isopropyl alcohol following dermal application. However, the extent of that exposure has not been fully characterized.

In a dermal exposure study in rats, 70 percent aqueous isopropyl alcohol solution was applied to a 4.5 square centimeter area of skin on the shaved backs of male and female Fischer F–344 rats and maintained under a sealed chamber for a period of 4 hours (Ref. 212). Most of the drug (approximately 85 percent of the dose) was recovered from the application site (i.e, was not absorbed). The remainder of the dose (approximately 15 percent) was detected in the blood within 1 hour after application, indicating that dermal exposure resulted in some systemic exposure. Maximum blood concentrations of isopropyl alcohol were attained at 4 hours and decreased steadily following removal of the test material. The half-life of elimination (T½) of isopropyl alcohol from blood was 0.77 and 0.94 hours for male and female rats, respectively. AUC was not determined.

Martinez, *et al.* compared isopropyl alcohol blood levels in rabbits after oral, dermal, and inhalation exposure (Ref. 213). Male rabbits (unidentified strain, three animals per group) were given 2 or 4 g/kg isopropyl alcohol via oral gavage, or unknown doses of isopropyl alcohol via inhalation exposure with or without concomitant dermal exposure. Isopropyl alcohol blood levels were measured for up to 4 hours after the initiation of treatment. The highest blood isopropyl alcohol concentrations were observed from the oral route of administration (262 and 278 mg/dL in the 2 and 4 g/kg groups, respectively). The dermal and inhalation groups produced a mean blood isopropyl alcohol concentration of 112 mg/dL. The inhalation-only group had a mean blood concentration of 6 to 8 mg/dL. However, the study provides little information regarding the bioavailability of dermally applied isopropyl alcohol because of the unknown dosing for the group given isopropyl alcohol via the combination of inhalation and dermal exposures.

The available animal ADME data from non-dermal routes of exposure are sufficient to characterize the absorption, distribution, metabolism, and excretion of isopropyl alcohol. Isopropyl alcohol is rapidly absorbed following oral ingestion and inhalation (Ref. 214). Isopropyl alcohol is metabolized to acetone in both animals and man by the hepatic enzyme alcohol dehydrogenase and is then metabolized further to carbon dioxide through a variety of metabolic pathways (Refs. 215 and 216). In animals, the excretion of isopropyl alcohol is pulmonary with approximately 3 to 8 percent excreted in the urine (Ref. 214). In humans, isopropyl alcohol is predominantly eliminated in the urine with a small amount being excreted through expiration (Ref. 217).

Slauter, *et al.* characterized the disposition and pharmacokinetics of isopropyl alcohol following intravenous (IV), oral (single and multiple doses), and inhalation exposure in male and female F–344 rats and B6C3F1mice (Ref. 214). Animals were exposed to either an IV dose of 300 mg/kg, inhalation of 500 or 5,000 parts per million isopropyl alcohol for 6 hours, single oral doses of 300 mg/kg or 3,000 mg/kg, or multiple doses of 300 mg/kg for 8 days. AUC and T½ were calculated based on the study data. No major differences in the rate or route of elimination between sexes or routes of exposure were demonstrated, and repeated exposure had no effect on excretion. However, the rate of elimination was shown to be dose-dependent, with higher doses increasing the T½. Isopropyl alcohol and its metabolites were distributed to all tissues without accumulation in any particular organ. While these data are adequate to define the ADME profile of isopropyl alcohol following non-dermal exposure, they are not sufficient to characterize what would occur following dermal exposure. Absorption data following dermal absorption in animals are still needed in order to determine the extent of systemic exposure following maximal dermal exposure to isopropanol-containing health care antiseptic products. Information on the distribution, metabolism, and excretion of isopropyl alcohol can be extrapolated from published data on the other routes of exposure.

*Isopropyl alcohol carcinogenicity data.* No data exist for the carcinogenicity potential of isopropyl alcohol following oral or dermal exposure in humans. The International Agency for Research on Cancer (IARC) monograph states that there is inadequate evidence of carcinogenicity of isopropyl alcohol in humans (Ref. 218). The IARC monograph indicates that an increased incidence of cancer of the paranasal sinuses was observed in workers at factories where isopropyl alcohol was manufactured by the strong-

acid process. In this instance, the primary route of exposure was through inhalation, rather than topical. The risk for laryngeal cancer may also have been elevated in these workers. However, it is unclear whether the cancer risk was caused by the presence of isopropyl alcohol itself or one of its by-products (diisopropyl sulfate, which is an intermediate in the process; or isopropyl oils, which are formed as by-products; or to other chemicals, such as sulfuric acid).

Inhalation carcinogenicity studies have been performed in animals to assess the potential carcinogenicity of isopropyl alcohol for industrial workers under occupational exposure conditions (Ref. 219). In a study in Fisher 344 rats and CD–1 mice by Burleigh-Flayer, *et al.*, high-dose treated rats had higher mortality rates and shorter survival times compared to controls. However, lower exposure groups of rats and mice did not experience significant increases in any tumors following exposure to isopropyl alcohol via the inhalation route for up to 2 years (Ref. 219). Groups of animals were exposed via whole-body exposure chambers to 0 (control), 500 (low-dose), 2,500 (mid-dose) or 5,000 (high-dose) parts per million of isopropyl alcohol vapor 6 hours per day, 5 days per week for up to 78 weeks in CD–1 mice (55/sex/dose) and 104 weeks in Fischer 344 rats (65/sex/dose). These respective isopropyl alcohol exposure levels in the low-dose, mid-dose, and high-dose groups correspond to doses of approximately 570, 2,900, and 5,730 mg/kg/day in mice, and 350, 1,790, and 3,530 mg/kg/day in rats. At the end of treatment, a large panel of organs was collected from control and high-dose treated groups for histopathological examination. In the mid- and low-dose groups, only kidneys and testes were examined.

No increases in the incidence of neoplastic lesions were observed in either mice or rats. In mice, no differences in the mean survival time were noted for any of the exposure groups. No increases in the incidence of neoplastic lesions were noted from treatment groups in either sex. In rats, survival was poor in males but adequate in females; none of the high-dose males survived beyond 100 weeks of dosing. The mean survival time was 631 and 577 days ($p < 0.01$) for the control and high-dose groups, respectively. No difference in mean survival time was noted for female rats. The main cause of death was chronic renal disease. Concentration-related increases in the incidence of interstitial cell adenoma of the testes were observed in male rats; however, this type of tumor is common among aged rats and was not considered to be treatment related. No increased incidence of other neoplastic lesions was observed in male rats, and no increased incidence of neoplastic lesions was observed for female rats from any exposure group.

No dermal carcinogenicity studies of isopropyl alcohol have been completed in animals, and little dermal data from other sources are available. In a subchronic 1-year dermal toxicity study, Rockland mice (30 per group) were treated three times weekly for 1 year with isopropyl alcohol (Ref. 216). No skin tumors were observed, but the sex, dose, and observation period were not specified. Although no evidence of carcinogenic potential was seen in this study, it was not long enough to be considered adequate for the assessment of the carcinogenicity potential of isopropyl alcohol via the dermal route.

*Isopropyl alcohol DART data.* A number of fertility and multigenerational studies were conducted for isopropyl alcohol administered via the oral route of exposure (Refs. 220 through 225). Isopropyl alcohol was associated with maternal toxicity when pregnant animals were exposed to high doses during pregnancy, but no teratogenic effects were noted on the pups. Isopropyl alcohol was not found to be teratogenic in rats in a number of studies using the oral exposure route using a 2-generation study design. Adverse effects noted for postnatal pups treated at high doses of isopropyl alcohol were limited to decreased pup body weights and increased liver weights (Ref. 221). Based on the weight of evidence from several studies, Faber and colleagues calculated the no observed adverse effect level (NOAEL) for pup postnatal survivability as 700 mg/kg/day in rats (Ref. 221). However, using an alternative, quantitative approach that takes dose-response information into account (*i.e.,* benchmark dose approach), other researchers have estimated a benchmark dose of 420 mg/kg/day (Ref. 226). In conclusion, additional DART data are not needed to support a GRAS determination for health care antiseptic products containing isopropyl alcohol.

*Isopropyl alcohol data on hormonal effects.* Studies evaluating hormonal effects of isopropyl alcohol are limited. We found only one study in the literature, which showed that exposure to high levels of isopropyl alcohol via the intraperitoneal route was associated with some perturbations in brain hormones (*e.g.,* dopamine, noradrenaline, and serotonin) (Ref. 227). The significance of these changes in hormone levels on the long-term development of the treated pups has not been evaluated. Overall, this study is not adequate to characterize the potential for hormonal effects of isopropyl alcohol. The existing data come from a single study, using a route of exposure that is not relevant to health care antiseptics, and the study did not evaluate other important types of hormones (*e.g.,* thyroid, sex hormones). Additional data to characterize the potential for hormonal effects of isopropyl alcohol are still needed to make a GRAS determination.

*Isopropyl alcohol resistance data.* We found no reports of bacterial resistance to isopropyl alcohol. Like alcohol, the antimicrobial mechanism of action of isopropyl alcohol is nonspecific, primarily caused by denaturation and coagulation of proteins (Refs. 146 through 149). High concentrations of isopropyl alcohol are toxic to most microorganisms due to its high oxygen demand and membrane-disruptive characteristics (Ref. 228). Because of isopropyl alcohol's speed of action and multiple, nonspecific toxic effects, microorganisms have a difficult time developing resistance to it.

Isopropyl alcohol is a common, cheap industrial solvent and researchers have been attempting to develop isopropyl alcohol-tolerant bacteria for use in biological treatment of isopropyl alcohol-containing industrial waste. A recent study identified an isopropyl alcohol-tolerant strain of *Paracoccus denitrificans* that could grow in isopropyl alcohol at a concentration of 1.6 percent (Ref. 229), and a strain of *Bacillus pallidus* has been shown to grow in isopropyl alcohol up to 2.4 percent (Ref. 230). Thus, even isopropyl alcohol-tolerant strains could not survive in health care antiseptic products, which would contain at least 70 percent isopropyl alcohol (59 FR 31402 at 31442). Furthermore, isopropyl alcohol evaporates readily after topical application, so no antiseptic residue is left on the skin that could contribute to the development of resistance (Refs. 146 and 148). Consequently, the development of resistance as a result of health care antiseptic use is unlikely and additional data on the development of antimicrobial resistance to isopropyl alcohol are not needed to make a GRAS determination.

b. *Isopropyl alcohol safety data gaps.* In summary, our administrative record for the safety of isopropyl alcohol is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including

documentation of validation of the methods used to measure isopropyl alcohol and its metabolites;

- animal ADME (dermal absorption);
- oral carcinogenicity;
- dermal carcinogenicity; and
- potential hormonal effects.

8. Triclocarban

In the 1994 TFM, FDA proposed to classify triclocarban as GRAS for all health care antiseptic uses. FDA is now proposing to classify triclocarban as Category III. The GRAS determination in the 1994 TFM was based on safety data and information that were submitted in response to the 1978 TFM on triclocarban formulated as bar soap (Ref. 231). These data included blood levels, target organs for toxicity, and no effect levels and were discussed in the 1991 First Aid TFM (56 FR 33644 at 33664). The existing data, however, need to be supplemented to fully evaluate the safety of triclocarban according to current scientific standards. New information regarding potential risks from systemic absorption and long-term exposure to antiseptic active ingredients is leading us to propose additional safety testing.

As discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76461–76462), FDA has reviewed the following:

- Human absorption data (Refs. 231 through 235);
- animal ADME data (Refs. 231 and 236 through 240);
- a 2-year oral carcinogenicity study of triclocarban in rats (Refs. 241 and 242); and
- data on hormonal effects (Refs. 42 and 43).

Based on our evaluation of these data, additional safety data are needed before triclocarban can be considered GRAS for use in a health care antiseptic.

*Triclocarban safety data gaps.* In summary, our administrative record for the safety of triclocarban is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure triclocarban and its metabolites;
- data to help define the effect of formulation on dermal absorption;
- animal ADME;
- dermal carcinogenicity;
- DART studies;
- potential hormonal effects; and
- data from laboratory studies that assess the potential for the development of resistance to triclocarban and cross-resistance to antibiotics as discussed in section VII.C.4.

9. Triclosan

In the 1994 TFM, FDA classified triclosan as lacking sufficient evidence of safety for use as a health care personnel hand wash and surgical hand scrub (59 FR 31402 at 31436). FDA is now proposing to classify triclosan as Category III for all health care uses. Since the 1994 TFM, a large number of studies have been conducted to characterize the toxicological and metabolic profile of triclosan using animal models. Most of these studies have focused on understanding the fate of triclosan following exposure to a single source of triclosan via the oral route of administration. However, dermal studies in both humans and animals are also available. These studies show that triclosan is absorbed through the skin, but to a lesser extent than oral absorption.

As discussed in the 2013 Consumer Wash PR (78 FR 76444 at 76467–76469), FDA has reviewed the following:

- Human absorption data (Refs. 243 through 248) in the consumer setting;
- animal ADME data (Refs. 243, 244, and 248 through 253) and determined that the data are not adequate and additional pharmacokinetic data (*e.g.,* AUC, Tmax, and Cmax) at steady-state levels continue to be necessary to bridge animal data to humans;
- short-term dermal toxicity studies in animals (Refs. 254 through 257) and determined that a long-term dermal carcinogenicity study is needed to assess the relevance of the short-term dermal toxicity findings to a chronic use situation;
- a 2-year oral carcinogenicity study of triclosan in hamsters (Refs. 258 and 259) and determined the data are adequate to show that triclosan does not pose a risk of cancer after repeated oral administration under the experimental conditions used;
- DART data (Refs. 260 and 261) and determined that the triclosan DART data are adequate and additional traditional DART studies are not necessary to make a GRAS determination;
- data on hormonal effects (Refs. 42, 44 through 48, 51, and 262) and determined that the consequences of short-term thyroid and reproductive findings on the fertility, growth, and development of triclosan-exposed litters could be addressed by studies in juvenile animals; and
- data on the potential for development of antimicrobial resistance and cross-resistance between triclosan and antibiotics (Refs. 61, 62 through 66, 69, 72, 74 through 77, and 263) and determined that triclosan exposure can change efflux pump activity and alter antibiotic susceptibilities, but data are still needed that would clarify the potential public health impact of the currently available data.

In addition to the data already reviewed in the 2013 Consumer Wash PR (78 FR 76444 at 76467), new data for some of the safety categories has also become available.

a. Summary of New Triclosan Safety Data

*New triclosan human pharmacokinetics data.* A recent biomonitoring study compared urine triclosan levels in a convenience sample of 76 health care workers in two hospitals (Ref. 264). One hospital used a 0.3 percent triclosan-containing soap in all patient care areas and restrooms. The second hospital used plain soap and water, having previously phased out triclosan-containing soaps. Both hospitals also had alcohol-based hand rub available. The use of triclosan-containing toothpaste and other personal care products was assessed through a questionnaire. Although the urinary concentrations of total (nonconjugated plus conjugated) triclosan were higher in health care workers that worked at the hospital using triclosan-containing soap, the use of triclosan-containing toothpaste was correlated with the highest urinary triclosan levels.

This study provides some information about health care worker exposure to triclosan, but it does not attempt to measure triclosan exposure under maximal use conditions. In summary, although human absorption of triclosan has been adequately characterized for moderate daily use, such as in the consumer setting, studies to evaluate maximal use in the health care setting are not available and MUsT data are needed to make a GRAS determination.

*New triclosan carcinogenesis data.* A recent study examined the effect of triclosan treatment on the development of liver cancer in mice (Ref. 265). Oral exposure to triclosan at a daily dose of approximately 68.6 mg/kg for 8 months resulted in the proliferation of liver cells (hepatocytes); elevated accumulation of collagen in the liver, which is an indicator of fibrosis of the liver; and oxidative stress. Collectively, these findings suggest that long-term triclosan treatment in mice can lead to the type of liver injury that is a risk factor for the development of liver cancer (hepatocellular carcinoma).

The ability of triclosan to function as a tumor promoter (*i.e.,* something that stimulates existing tumors to grow) also was evaluated. Male mice were pretreated with a single injection of a

chemical that can initiate tumors (diethylnitrosamine (DEN)). Test mice then received triclosan at approximately 28.6 mg/kg in their drinking water while control mice received untreated water for 6 months. Triclosan-treated mice had a higher number of liver tumors, larger tumor size, and greater tumor incidence than mice given DEN alone, suggesting that triclosan may be a tumor promoter for other carcinogens in the liver. The authors conclude that long-term triclosan treatment substantially accelerates the development of hepatocellular carcinoma in mice. The relevance of this study to humans, however, is not clear. The concentrations of triclosan used in this study are likely much higher than the concentrations that health care workers would be exposed to during antiseptic use. We invite comment on what these findings tell us about triclosan's potential impact on human health and the submission of additional data on this subject.

*New triclosan findings on muscle function.* In the 2013 Consumer Wash PR, we described a study on the physiological effects of triclosan treatment on muscle function in mice and fish (Ref. 266). A newer study further examined the physiological effects of triclosan treatment on muscle function in fish (Ref. 267). This study examined whether triclosan's effect on fish swimming performance correlates with altered messenger ribonucleic acid (mRNA) and protein expression of genes known to be critical for muscle function, and supports the negative effects on muscle function seen in the previous study. We invite comment on what these findings tell us about triclosan's potential impact on human health and the submission of additional data on this subject.

*New triclosan data on hormonal effects.* The studies reviewed in the 2013 Consumer Wash PR have demonstrated that triclosan has effects on the thyroid, estrogen, and testosterone systems in several animal species, including mammalian species (Refs. 42, 44 through 48, 51, and 262). A recent report describes two studies of the effect of triclosan exposure on thyroid hormone levels in pregnant and lactating rats, and in directly exposed offspring (Ref. 268). Pregnant rats (dams) were treated with 75, 150, or 300 mg triclosan per kilogram of body weight per day (mg/kg bw/day) throughout gestation and the lactation period by gavage. Total thyroxine ($T_4$) serum levels were measured in both the dams and offspring, which had indirect exposure to triclosan through the placenta and maternal milk. All doses of triclosan significantly lowered $T_4$ levels in dams, but no significant effects on $T_4$ levels were seen in the offspring at the end of the lactation period. In the second study, pups were dosed directly (gavaged) with 50 or 150 mg triclosan/kg bw/day from postnatal day 3 to 16. Significant reductions in the $T_4$ levels of 16-day-old offspring in both dose groups were noted. This study corroborates the effects on the thyroid seen in previous animal studies, but does not provide long-term data on the hormonal effects of triclosan exposure. Another new study showed that when triclosan was administered directly into the stomach (*i.e.,* intragastrically) of adult rats at doses of 10, 50, and 200 mg/kg for 8 weeks, it resulted in a significant decrease in daily sperm production, changes in sperm morphology, and epididymal histopathology in rats treated with the highest dose of triclosan (Ref. 269).

The information in these studies has not changed our assessment of the need for additional data on hormonal effects. At this time, no adequate long-term (*i.e.,* more than 30 days) in vivo animal studies have been conducted to address the consequences of these hormonal effects on functional endpoints of growth and development (*e.g.,* link of preputial separation to sexual differentiation and fertility, link of decreased thyroxine/triiodothyronine to growth and neurobehavioral development) in exposed fetuses or pups. Studies in juvenile animals (of the type described in section VII.C.3) could address the consequences of short-term thyroid and reproductive findings on the fertility, growth, and development of triclosan-exposed litters.

*New triclosan resistance data.* The studies reviewed in the 2013 Consumer Wash PR showed that bacterial species with reduced susceptibility to triclosan were also resistant to one or more of the tested antibiotics (Refs. 61 through 66, 69, 72, 74 through 77, and 263). Several studies suggested that an efflux mechanism is responsible for the observed reduced triclosan susceptibility in some of the bacteria exhibiting resistance (Refs. 66, 69, 76, and 109). Newer studies have further characterized efflux pump activity in response to triclosan in a variety of these bacterial species (Refs. 110 and 270 through 274). Although the clinical relevance of these studies is not clear, the possibility that triclosan contributes to changes in antibiotic susceptibility warrants further evaluation.

In addition to bacterial efflux activity, other mechanisms have been described that may also contribute to reduced triclosan susceptibility. At low concentrations, triclosan can inhibit an essential bacterial enzyme (enoyl-acyl carrier protein reductase) involved in fatty acid synthesis (Refs. 275 and 276). In bacteria, four enoyl-acyl carrier protein reductases have been identified: FabI, FabK, FabL, and FabV (Refs. 276 and 277). Several recent studies have further characterized the effect of triclosan on enoyl-acyl carrier protein reductases in different bacterial species, which confirmed that over-expression of the *fabI* gene results in reduced triclosan susceptibility in *S. aureus* (Ref. 278), demonstrated that FabV can confer resistance to triclosan in *Pseudomonas aeruginosa* (Ref. 279), and refuted the theory that FabK from *Enterococcus faecalis* is responsible for the inherent triclosan resistance of this organism (Ref. 280). Taken together, these studies suggest that some bacteria have multiple mechanisms that can be used to survive in the presence of triclosan.

A recent study analyzed 1,388 clinical isolates of *S. aureus* to determine their triclosan susceptibilities (Ref. 79). Sixty-eight strains that exhibited reduced susceptibility to triclosan, defined as a minimum bactericidal concentration greater than 4 mg/L, were chosen for further characterization, including sequencing of the *fabI* gene. Previous studies have shown that mutations in, or overexpression of, the *fabI* gene can result in reduced susceptibility to triclosan (Ref. 275). Among the 68 clinical isolates with reduced susceptibility to triclosan, only 30 had a mutation in the *fabI* gene, while 38 strains had a normal (wild-type) *fabI* gene. Further molecular analysis identified novel resistance mechanisms linked to the presence of an additional, alternative *fabI* gene derived from another species of *Staphylococcus* in some of the strains, which was most likely acquired by horizontal transfer (the transmission of DNA between different organisms, rather than from parent to offspring). Clinical *S. aureus* strains with decreased susceptibility to triclosan had a strong association with the presence of a mutated *fabI* gene or the alternative *fabI* gene ($P < 0.001$). The authors suggest that this finding is the first clear evidence that utilization of antiseptics can drive development of antiseptic resistance in clinical isolates. The possibility that an antiseptic may drive the development of resistance and the possibility of horizontal transfer of resistance determinants to clinical isolates warrant further evaluation.

Other studies have evaluated the antiseptic and antibiotic susceptibility profiles of clinical isolates or isolates of bacteria associated with specific hospital outbreaks. In one study, the

triclosan susceptibility of clinical isolates of *S. epidermidis* isolated from blood cultures of patients that were collected prior to the introduction of triclosan (during 1965–1966, ''old'' isolates) was compared to modern isolates, collected in 2010–2011 (Ref. 281). None of the isolates from 1965–1966 were tolerant to triclosan; however, 12.5 percent of the modern isolates had decreased triclosan susceptibility, with MIC values that were up to 32-fold higher than the highest value found in the old isolates. When triclosan-susceptible strains were grown in increasing concentrations of triclosan, both old and modern isolates could be adapted to the same triclosan MIC level as found in modern tolerant isolates. Although this study suggests that decreased susceptibility to triclosan can occur in relevant organisms as a result of triclosan exposure, the source(s) and extent of triclosan exposure for the modern isolates are unknown, which makes the relevance of these data to the clinical setting unclear.

In another recent study (Ref. 282), the antimicrobial activity of triclosan was evaluated for a multidrug-resistant strain of *P. aeruginosa* that had caused an outbreak in an oncohematology unit in Italy (Ref. 283). Experimental exposure to triclosan has been shown to lead to changes in bacterial efflux pump activity, which can result in antibiotics being removed from the bacterial cell and bacterial resistance (Ref. 66). The authors of this study examined whether triclosan exposure increased the level of antibiotic resistance in the outbreak strain. The outbreak strain was adapted to grow in the presence of triclosan by serial passage in gradually increasing triclosan concentrations, up to 3,400 mg/L triclosan. Then, the susceptibility of triclosan-adapted and unadapted *P. aeruginosa* to a panel of antibiotics that are typically exported by efflux pumps, namely tetracycline, ciprofloxacin, amikacin, levofloxacin, carbenicillin, and chloramphenicol, was determined. For all antibiotics examined, the MIC of the triclosan-adapted strain was 2-fold higher than the unadapted strain. The addition of efflux pump inhibitors reduced the MICs 2- to 4-fold for both strains and all antibiotics examined, suggesting that an efflux pump mechanism is involved in the reduced susceptibility. Despite the trend for the triclosan-adapted strain to be less susceptible to the tested antibiotics, the differences were very modest and the clinical relevance of these small changes in MIC, if any, are not known.

Overall, the administrative record for triclosan is complete on the following aspects of the resistance issue:

- Laboratory studies demonstrate triclosan's ability to alter antibiotic susceptibilities (Refs. 61 through 66, 69, 72, 74 through 77, and 263).
- Data define triclosan's mechanisms of action and demonstrate that these mechanisms are dose dependent (Ref. 113).
- Data demonstrate that exposure to triclosan changes efflux pump activity, a common nonspecific bacterial resistance mechanism (Refs. 66, 69, 76, and 109).
- Data show that low levels of triclosan may persist in the environment (Refs. 91, 116, 117, and 284 through 289).

However, the administrative record is not complete with respect to data that would clarify the potential public health impact of the currently available data. Examples of the type of information that could be submitted to complete the record include the following:

- Data to characterize the concentrations and antimicrobial activity of triclosan in various biological and environmental compartments (*e.g.,* on the skin, in the gut, and in environmental matrices);
- data to characterize the antiseptic and antibiotic susceptibility levels of environmental isolates in areas of prevalent antiseptic use, *e.g.,* in health care, food handler, and veterinary settings; and
- data to characterize the potential for the reduced antiseptic susceptibility caused by triclosan to be transferred to other bacteria that are still sensitive to triclosan.

b. Triclosan Safety Data Gaps.

In summary, our administrative record for the safety of triclosan is incomplete with respect to the following:

- Human pharmacokinetic studies under maximal use conditions when applied topically (MUsT), including documentation of validation of the methods used to measure triclosan and its metabolites;
- animal ADME;
- dermal carcinogenicity;
- potential hormonal effects; and
- data to clarify the relevance of antimicrobial resistance laboratory findings to the health care setting.

## VIII. Proposed Effective Date

Based on the currently available data, this proposed rule finds that additional data are necessary to establish the safety and effectiveness of health care antiseptic active ingredients for use in OTC health care antiseptic drug products. Accordingly, health care antiseptic active ingredients would be nonmonograph in any final rule based on this proposed rule. We recognize, based on the scope of products subject to this monograph, that manufacturers will need time to comply with a final rule based on this proposed rule. However, because of the potential effectiveness and safety considerations raised by the data for some antiseptic active ingredients evaluated, we believe that an effective date later than 1 year after publication of the final rule would not be appropriate or necessary. Consequently, any final rule that results from this proposed rule will be effective 1 year after the date of the final rule's publication in the **Federal Register**. On or after that date, any OTC health care antiseptic drug product that is subject to the monograph and that contains a nonmonograph condition, *i.e.,* a condition that would cause the drug to be not GRAS/GRAE or to be misbranded, could not be introduced or delivered for introduction into interstate commerce unless it is the subject of an approved new drug application or abbreviated new drug application. Any OTC health care antiseptic drug product subject to the final rule that is repackaged or relabeled after the effective date of the final rule would be required to be in compliance with the final rule, regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

## IX. Summary of Preliminary Regulatory Impact Analysis

The summary analysis of benefits and costs included in this proposed rule is drawn from the detailed Preliminary Regulatory Impact Analysis (PRIA) that is available at *http://www.regulations.gov,* Docket No. FDA–2015–N–0101 (formerly Docket No. FDA–1975–N–0012).

### *A. Introduction*

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule could impose significant economic burdens on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any 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 annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA expects that this proposed rule could result in a 1-year expenditure that would meet or exceed this amount.

*B. Summary of Costs and Benefits*

The proposed rule's costs and benefits are summarized in table 12 entitled ''Economic Data: Costs and Benefits Statement.'' Benefits are attributed to reducing the potential adverse health effects associated with exposure to antiseptic active ingredients in the event that any active ingredient is shown to be unsafe or ineffective for chronic use. Annual benefits are estimated to range between $0 and $0.16 million. We estimate the present value associated with $0.16 million of annual benefits, over a 10-year period, to approximately equal $1.4 million at a 3 percent discount rate and $1.1 million at a 7 percent discount rate.

Costs include the one-time costs associated with reformulating products, relabeling reformulated products, and conducting both safety and efficacy tests. We estimate one-time upfront costs to approximately range between $64.0 million and $90.8 million. Annualizing these costs over a 10-year period, we estimate total annualized costs to range from $7.3 and $10.4 million at a 3 percent discount rate to $8.5 and $12.1 million at a 7 percent discount rate.

FDA also examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. The rule could impose a significant economic impact on a substantial number of small entities. For small entities, we estimate the rule's costs to roughly range between 0.01 and 82.18 percent of average annual revenues. In the Initial Regulatory Analysis, we assess several regulatory options that would reduce the proposed rule's burden on small entities. These options include extending testing compliance time to 24 months (rather than 12 months), and extending relabeling compliance times to 18 months (rather than 12 months).

The full discussion of economic impacts is available in Docket No. FDA–2015–N–0101 *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

TABLE 12—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

| Category | Low estimate | Median estimate | High estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|
| | | | | Year dollars | Discount rate (percent) | Period covered (years) | |
| Benefits: | | | | | | | |
| Annualized Monetized $millions/year. | 0.0 | $0.08 | $0.16 | 2013 | 7 | 10 | Value of reduced number of adverse events associated with using non-GRAS/GRAE antiseptic active ingredients. Range of estimates captures uncertainty. |
| Annualized Monetized $millions/year. | 0.0 | 0.08 | 0.16 | 2013 | 3 | 10 | |
| Annualized Quantified billion/year. | 0 | 10.3 | 20.6 | ..... | 7 | 10 | Reduced antiseptic active ingredient exposure (in milliliters). Range of estimates captures uncertainty. |
| Annualized Quantified billion/year. | 0 | 10.3 | 20.6 | ..... | 3 | 10 | |
| Qualitative ..... | Value of infection avoidance associated with switching from non-GRAS/GRAE antiseptic active ingredients to NDA or ANDA antiseptics. | | | | | | |
| Costs: | | | | | | | |
| Annualized Monetized $millions/year. | 8.5 | 10.3 | 12.1 | 2013 | 7 | 10 | Annualized costs of reformulating and testing antiseptic products. Range of estimates capture uncertainty. |
| Annualized Monetized $millions/year. | 7.3 | 8.9 | 10.4 | 2013 | 3 | 10 | |
| Annualized Quantified billion/year. | ..... | ..... | ..... | ..... | 7 | | |
| Annualized Quantified billion/year. | ..... | ..... | ..... | ..... | 3 | | |
| Qualitative ..... | Where the products affected by this proposed rule are currently chosen over NDA and ANDA alternatives (such as chlorhexidine products), a switch brought on by the rule may lead to search costs or other types of transactions costs. In this scenario, there are also the potential costs associated with adverse reactions if patients are allergic to substitute products. | | | | | | |

TABLE 12—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT—Continued

| Category | Low estimate | Median estimate | High estimate | Units | | | Notes |
|---|---|---|---|---|---|---|---|
| | | | | Year dollars | Discount rate (percent) | Period covered (years) | |
| Transfers: | | | | | | | |
| Federal Annualized | | | | | 7 | | |
| Monetized $millions/year. | | | | | 3 | | |
| From/To. | | | | | | | |
| Other Annualized | | | | | 7 | | |
| Monetized $millions/year. | | | | | 3 | | |
| From/To. | | | | | | | |

Effects:
State, Local, or Tribal Government: Not applicable.
Small Business: The costs associated with potentially affected small entities range between 0.01 and 82.18 percent of their average annual revenues.
Wages: No estimated effect.
Growth: No estimated effect.

## X. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## XI. Environmental Impact

We have determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## XII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would have a preemptive effect on State law. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 751 of the FD&C Act (21 U.S.C. 379r) is an express preemption provision. Section 751(a) of the FD&C Act provides that no State or political subdivision of a State may establish or continue in effect any requirement that: (1) Relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A) of the FD&C Act and (2) is different from or in addition to, or that is otherwise not identical with, a requirement under the FD&C Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 *et seq.*), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*). Currently, this provision operates to preempt States from imposing requirements related to the regulation of nonprescription drug products. (See section 751(b) through (e) of the FD&C Act for the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.)

This proposed rule, if finalized as proposed, would remove from the health care antiseptic monograph any active ingredient for which the additional safety and effectiveness data required to show that a health care antiseptic product containing that ingredient would be GRAS/GRAE have not become available. Any final rule would have a preemptive effect in that it would preclude States from issuing requirements related to OTC health care antiseptics that are different from, in addition to, or not otherwise identical with a requirement in the final rule. This preemptive effect is consistent with what Congress set forth in section 751 of the FD&C Act. Section 751(a) of the FD&C Act displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision is not applicable, implied preemption may arise (see *Geier* v. *American Honda Co.,* 529 U.S. 861 (2000)).

FDA believes that the preemptive effect of the proposed rule, if finalized, would be consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposed to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA is providing an opportunity for State and local officials to comment on this rulemaking.

## XIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this proposed rule publishes in the **Federal Register**.)


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### List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310, as proposed to be amended December 17, 2013, at 78 FR 76444, is proposed to be further amended as follows:

## PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 2. Amend § 310.545 as follows:
■ a. Add reserved paragraph (a)(27)(v);
■ b. Add paragraphs (a)(27)(vi) through (x);
■ c. In paragraph (d) introductory text, remove''(d)(39)'' and in its place add ''(d)(42)''; and
■ d. Add paragraph (d)(42).

The additions read as follows:

### § 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *
(27) * * *
(v) [Reserved]
(vi) *Health care personnel hand wash drug products.* Approved as of [*DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER*].

Benzalkonium chloride
Benzethonium chloride
Chloroxylenol
Cloflucarban
Fluorosalan
Hexachlorophene
Hexylresorcinol
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
Methylbenzethonium chloride
Nonylphenoxypoly (ethyleneoxy) ethanoliodine
Phenol
Poloxamer iodine complex
Povidone-iodine
Secondary amyltricresols

Sodium oxychlorosene
Tribromsalan
Triclocarban
Triclosan
Undecoylium chloride iodine complex

(vii) *Health care personnel hand rub drug products.* Approved as of [*DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER*].

Alcohol (ethanol and ethyl alcohol)
Benzalkonium chloride
Isopropyl alcohol

(viii) *Surgical hand scrub drug products.* Approved as of [*DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER*].

Benzalkonium chloride
Benzethonium chloride
Chloroxylenol
Cloflucarban
Fluorosalan
Hexachlorophene
Hexylresorcinol
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
Methylbenzethonium chloride
Nonylphenoxypoly (ethyleneoxy) ethanoliodine
Phenol
Poloxamer iodine complex
Povidone-iodine
Secondary amyltricresols
Sodium oxychlorosene
Tribromsalan
Triclocarban
Triclosan
Undecoylium chloride iodine complex

(ix) *Surgical hand rub drug products.* Approved as of [*DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER*].

Alcohol (ethanol and ethyl alcohol)
Isopropyl alcohol

(x) *Patient preoperative skin preparation drug products.* Approved as of [*DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER*].

Alcohol (ethanol and ethyl alcohol)
Benzalkonium chloride
Benzethonium chloride
Chloroxylenol
Cloflucarban
Fluorosalan
Hexachlorophene
Hexylresorcinol
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
Iodine tincture
Iodine topical solution
Isopropyl alcohol
Mercufenol chloride
Methylbenzethonium chloride
Nonylphenoxypoly (ethyleneoxy) ethanoliodine
Phenol
Poloxamer iodine complex
Povidone-iodine
Secondary amyltricresols
Sodium oxychlorosene
Tribromsalan
Triclocarban
Triclosan
Triple dye
Undecoylium chloride iodine complex
Combination of calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative
Combination of mercufenol chloride and secondary amyltricresols in 50 percent alcohol

* * * * *

(d) * * *

(42) [*DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER*], for products subject to paragraphs (a)(27)(vi) through (a)(27)(x) of this section.

Dated: April 27, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–10174 Filed 4–30–15; 8:45 am]

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