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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AN03

Federal Employees Health Benefits Program Miscellaneous Changes: Medically Underserved Areas

AGENCY: U.S. Office of Personnel Management.

ACTION: Direct final rule.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a direct final rule to discontinue the annual determination of the Medically Underserved Areas (MUAs) for the Federal Employees Health Benefits (FEHB) Program.

DATES: Effective January 1, 2015. Comments due February 17, 2015.

ADDRESSES: Send written comments to Lynelle T. Frye, Policy Analyst, Planning and Policy Analysis, U.S. Office of Personnel Management, Room 4312, 1900 E Street NW., Washington, DC; or FAX to (202) 606–4640 Attn: Lynelle T. Frye. You may also submit comments using the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Lynelle T. Frye, Policy Analyst, at (202) 606–0004 or email: *lynelle.frye@opm.gov.*

SUPPLEMENTARY INFORMATION: Due to the enactment of Section 2706(a) of the Public Health Service Act (PHSA), OPM has concluded that the annual determination of Medically Underserved Areas (MUAs) for the FEHB Program is no longer required. Section 2706(a) of the PHSA requires that a health insurance issuer or group health plan offering coverage shall not discriminate with respect to coverage against any health care provider who performs covered services when acting within the scope of their license or certification under applicable state law in any area of a state.

Background

The Federal Employees Health Benefits (FEHB) law (5 U.S.C. 8902(m)(2)) requires that a State be designated as a Medically Underserved Area if 25% or more of the population lives in an area identified by the Department of Health and Human Services (HHS) as a primary medical care manpower shortage area.

It is intended to provide special consideration for enrollees who obtain health services in states with critical shortages of primary care physicians. As such, FEHB fee-for-service plans are required to provide benefits for covered services (subject to their contract terms) provided by any licensed provider practicing within the scope of his/her license, such as physician assistants or nurse midwives, which otherwise may not be considered as covered providers by the fee-for-service plan.

After the enactment of Section 2706(a) of the Public Health Service Act (PHSA) the Department of Labor offered guidance to health plans and health insurance issuers that, to the extent an item or service is a covered benefit under the plan or coverage, and consistent with reasonable medical management techniques specified under the plan with respect to the frequency, method, treatment or setting for an item or service, a plan or issuer shall not discriminate based on a provider's license or certification, to the extent the provider is acting within the scope of the provider's license or certification under applicable state law. This provision does not require plans or issuers to accept all types of providers into a network. This provision also does not govern provider reimbursement rates, which may be subject to quality, performance, or market standards and considerations.

The effect of Section 2706(a) of the PHSA is to expand the geographic area of coverage for all licensed providers offering covered services within the scope of their license to all areas of all States rather than the only those areas designated as Medically Underserved under 5 U.S.C. 8902(m)(2).

OPM has concluded that Section 2706(a) of the PHSA renders the annual determination of the MUAs for FEHB no longer required. It serves a similar purpose, since this Section is to expand the geographic area of coverage for all licensed providers offering covered services within the scope of their license to all areas of all States rather than the only those areas designated as Medically Underserved under 5 U.S.C. 8902(m)(2).

With this change, we are not seeking a comment period since we feel it serves the same purpose as MUA.

Regulatory Impact Analysis

OPM has examined the impact of this proposed rule as required by Executive Order 12866 and Executive Order 13563, which directs 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 must be prepared for major rules with economically significant effects of $100 million or more in any one year. This rule is not considered a major rule because there will be a minimal impact on costs to Federal agencies.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation only affects health insurance benefits of Federal employees and annuitants.

Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles, and responsibilities of State, local, or Tribal governments.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; see 5 CFR part 1320) requires that the U.S. Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented.

Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. OPM is not proposing any additional collections in this rule.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure; Government employees; Health facilities; Health insurance; Health professions; Hostages; Iraq; Kuwait; Lebanon; Military personnel; Reporting and recordkeeping requirements; Retirement.

U.S. Office of Personnel Management.

Kathleen Archuleta,

Director.

Accordingly, OPM is amending 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.301 also issued under sec. 311 of Pub. L. 111–03, 123 Stat. 64; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521; Sec. 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604; 5 U.S.C. 8913; Sec. 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; Sec. 890.102 also issued under sections 11202(f), 11232(e), 11246 (b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061; Pub. L. 111–148, as amended by Pub. L. 111–152.

Subpart G—[Removed and Reserved]

■ 1. Remove and Reserve subpart G, consisting of §§ 890.701 and 890.702.

[FR Doc. 2014–29554 Filed 12–16–14; 8:45 am]

BILLING CODE 6325–63–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 744 and 774

[Docket No. 140813667–4667–01]

RIN 0694–AG27

Expansion of the Microprocessor Military End-Use and End-User Control

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is amending the microprocessor military end-use and end-user control in the Export Administration Regulations by expanding the scope of microprocessors subject to the restriction to harmonize with technological advances to microprocessor chips and expand the scope to include related software and technology for the development and production of these chips. In addition, this rule adds a prohibition on the use of license exceptions (including License Exception ENC) and otherwise expands license requirements for exports, reexports, or transfers (in-country) of microprocessors subject to the military end-use and end-user restriction. This expansion is consistent with the foreign policy objectives of the United States of preventing U.S. exports that might contribute to destabilizing military capabilities against the United States and its citizens. The foreign policy report explaining the expansion was sent to Congress on December 1, 2014. This rule also expands the scope of controls to cover in-country transfers, in order to control in-country transfers to prohibited military end users or end uses. BIS is also making editorial and format revisions to this section to improve clarity.

DATES: *Effective date:* This rule is effective December 17, 2014.

FOR FURTHER INFORMATION CONTACT: Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–2440 or by email at *Sharron.cook@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background

On January 14, 2003 (68 FR 1796), the Bureau of Industry and Security (BIS) published a rule to implement the microprocessor military end-user and end-use control in § 744.17 of the Export Administration Regulations (EAR). That rule imposed an end-use and end-user based license requirement on the export of certain microprocessors to military end uses and end users in countries in Country Group D:1 (see Supplement No. 1 to part 740 of the EAR).

End-use and end-user based controls are in addition to any controls based on the technical parameters of the item. Thus, the end-use and end-user based license requirements set forth in § 744.17 may apply to a transaction, even if the Commerce Country Chart indicates there are no license requirements, *i.e.,* no ''X'' in the box. When controls set forth under more than one section of the EAR apply to a transaction, the license requirements for such a transaction will be determined based on the requirements of all applicable sections of the EAR, and license applications will be reviewed under all applicable licensing policies.

To determine license requirements, one should follow the decision tree flowchart in Supplement No. 1 to part 732. An ECCN may have multiple license requirements, *e.g.,* CCL-based, end-use based, or end-user based. Also note that to use a license exception, each license requirement on an ECCN must be overcome.

Revisions to § 744.17 ''Restrictions on Certain Exports, Reexports and Transfers (in-country) of Microprocessors and Associated ''Software'' and ''Technology'' for 'Military End Uses' and to 'Military End Users'''

Since 744.17 was established, BIS's administration of export controls has increasingly focused on end uses and end users. Consistent with this change, BIS is adding in-country transfer controls to this section of the EAR to incorporate restrictions that would apply even if a transaction is licensed for a particular destination.

BIS is also expanding the scope of microprocessors requiring a license under § 744.17 by removing the specific ECCN (3A991.a.1) from the text, so that the prohibition applies to any microprocessor meeting the specified performance criteria, and associated ''software'' and ''technology.'' As encryption and other ''information security'' functionality has become more commonplace in hardware, BIS has concluded that microprocessors classified under any ECCN in Category 5—Part 2 of the EAR (including ECCN 5A992.c for 'mass market' encryption chips and ECCN 5A002 for a variety of non-'mass market' microprocessors) warrant the same license requirement as BIS currently requires under § 744.17 for the microprocessors classified outside of Category 5—Part 2, even if no license would be required (NLR) or License Exception ENC would otherwise be available. Because of this scope revision, the first sentence of paragraph (a) is revised to clarify that this license requirement is in addition to all license requirements set forth in the EAR and not just anti-terrorism reasons for control. Furthermore, BIS is expanding the scope of the license requirement in § 744.17 to include ''technology'' and ''software'' for the ''development'' and ''production'' of the microprocessors described in § 744.17(a).

In relation to § 744.17(f) ''Exceptions,'' BIS is also moving, from paragraph (a) to paragraph (f), text that exempted from § 744.17 personnel and agencies of the U.S. Government or agencies of a cooperating government under License Exception GOV. In

addition to harmonizing § 744.17(f) with recent changes in License Exception GOV, BIS is expanding paragraph (f) to include exports, reexports and transfers (in-country) ''on behalf of'' the U.S. Government or agencies of a cooperating government and updating and incorporating the related citation references.

BIS is also fixing the use of double and single quotes around the terms in this section to increase clarity. Single quotes are used for terms that are defined in a section where it appears, whereas double quotes indicate a term defined in § 772.1 of the EAR.

Revisions to the Supplement No. 1 to Part 774 ''Commerce Control List''

This rule adds a reference to the license requirements in § 744.17 in the affected ECCNs of the Commerce Control List. Specifically, ECCNs 3A001, 3D002, 3D991, 3E001, 3E002, 3E991, 5A002, 5A992, 5D002, 5D992, 5E002 and 5E992 are amended by adding a License Requirement Note after the Control Table in the License Requirements section. This reference in the ECCN may help prevent exporters from missing this combination item/end-use based license requirement.

ECCN 3A991 already had a license requirement note pointing to the license requirements in § 744.17. This rule replaces the existing note with the same one being added to the other twelve ECCNs in this rule.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 46957 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Savings Clause

Shipments of items removed from license exception eligibility or eligibility for export, reexport, or transfer (in-country) without a license as a result of this regulatory action that were on dock for loading, on lighter, laden aboard a carrier, or en route aboard a carrier to a port, on December 17, 2014, pursuant to actual orders to a destination, may proceed to that destination under the previous license exception eligibility or without a license so long as they have been exported, reexported, or transferred (in-country) before February 17, 2015. Any such items not actually exported, reexported, or transferred (in-country) before midnight, on February 17, 2015, require a license in accordance with this regulation.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and carries a burden estimate of 43.8 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). If this rule were delayed to allow for notice and comment and a delay in effective date, these high performance microprocessors, as well as associated development and production technology and software would continue to be exported, reexported and transferred (in-country) to military end uses or military end users to the detriment of the national security or foreign policy interests of the United States. In addition, publishing a proposed rule would give notice of the U.S. Government's intention to restrict the export, reexport and transfer of these items and would create an incentive to either accelerate exports, reexports and transfers of these items to conduct activities that are contrary to the national security or foreign policy interests of the United States, and/or to take steps to try to limit the impact of the this expanded control once a final rule was published. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

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

PART 744—[AMENDED]

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

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR

44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 21, 2014, 79 FR 3721 (January 22, 2014); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 78 FR 67035 (November 12, 2014).

■ 2. Revise § 744.17 to read as follows:

§ 744.17 Restrictions on certain exports, reexports and transfers (in-country) of microprocessors and associated ''software'' and ''technology'' for ''military end uses'' and to ''military end users.''

(a) *General prohibition.* In addition to the license requirements set forth elsewhere in the EAR, you may not export, reexport or transfer (in-country) microprocessors (''microprocessor microcircuits,'' ''microcomputer microcircuits,'' and microcontroller microcircuits having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality), or associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors without a license if, at the time of the export, reexport or transfer (in-country), you know, have reason to know, or are informed by BIS that the item will be or is intended to be used for a 'military end use,' as defined in paragraph (d) of this section, in a destination listed in Country Group D:1 (see Supplement No. 1 to part 740 of the EAR); or by a 'military end user,' as defined in paragraph (e) of this section, in a destination listed in Country Group D:1.

(b) *Additional prohibition on exporters or reexporters informed by BIS.* BIS may inform an exporter, reexporter or transferor, either individually by specific notice or through amendment to the EAR, that a license is required for export, reexport or transfer (in-country) of items described in paragraph (a) of this section to specified end users, because BIS has determined that there is an unacceptable risk of diversion to the end uses or end users described in paragraph (a) of this section. Specific notice is to be given only by, or at the direction of, the Deputy Assistant Secretary for Export Administration. When such notice is provided orally, it will be followed by a written notice within two working days signed by the Deputy Assistant Secretary for Export Administration. The absence of any such notification does not excuse the exporter, reexporter or transferor from compliance with the license requirements of paragraph (a) of this section.

(c) *License review standards.* There is a presumption of denial for applications to export, reexport or transfer (in-country) items subject to this section.

(d) *Military end-use.* In this section, the phrase 'military end use' means incorporation into: a military item described on the U.S. Munitions List (USML) (22 CFR part 121, International Traffic in Arms Regulations) or the Wassenaar Arrangement Munitions List (as set out on the Wassenaar Arrangement Web site at *http://www.wassenaar.org*); commodities classified under ECCNs ending in ''A018'' or under ''600 series'' ECCNs; or any commodity that is designed for the ''use,'' ''development,'' ''production,'' or deployment of military items described on the USML, the Wassenaar Arrangement Munitions List or classified under ECCNs ending in ''A018'' or under ''600 series'' ECCNs. Supplement No. 1 of this part lists examples of 'military end use.'

(e) *Military end user.* In this section, the term 'military end user' means the national armed services (army, navy, marine, air force, or coast guard), as well as the national guard and national police, government intelligence or reconnaissance organizations, or any person or entity whose actions or functions are intended to support 'military end uses' as defined in paragraph (d) of this section.

(f) *Exceptions.* The prohibitions described in paragraphs (a) and (b) of this section supersede any license exception or No License Required (NLR) designation that would otherwise apply to a transaction subject to the EAR, except that this license requirement does not apply to exports, reexports or transfers (in-country) of items for or on behalf of the official use by personnel and agencies of the U.S. Government or to agencies of a cooperating government authorized by License Exception GOV pursuant to § 740.11 of the EAR. See § 740.11(b)(1) of the EAR for the definition of 'agency of the U.S. Government' and § 740.11(c)(1) for the definition of 'agency of a cooperating government.'

PART 774—[AMENDED]

■ 3. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

Supplement No. 1 to Part 774—[Amended]

■ 4. In Supplement No. 1 to part 774 (the Commerce Control List), ECCNs 3A001, 3D002, 3D991, 3E001, 3E002, 3E991, 5A002, 5A992, 5D002, 5D992, 5E002 and 5E992 are amended by adding a License Requirement Note after the Control Table in the License Requirements section to read as follows:

Supplement No. 1 to Part 774—Commerce Control List

* * * * *

License Requirements

* * * * *

License Requirements Note: See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.

* * * * *

■ 5. In Supplement No. 1 to part 774 (the Commerce Control List), Category 3, ECCN 3A991 is amended by revising the License Requirements Notes to read as follows:

3A991 Electronic Devices, and ''Components'' Not Controlled by 3A001.

License Requirements

* * * * *

License Requirements Note: See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.

* * * * *

Dated: December 11, 2014.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2014–29450 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 154

[Docket No. RM14–21–000; Order No. 801]

Natural Gas Act Pipeline Maps

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: In this Final Rule, the Federal Energy Regulatory Commission revises its regulations governing interstate natural gas pipeline system maps. First, the Commission eliminates the requirements that pipelines include maps in their tariffs and file updated maps as part of their tariffs by the following April 30 for any year that there is a major change in the pipeline's system. Second, the Commission retains the requirement that pipelines post and maintain a system map on their Internet Web sites, and implements a quarterly deadline for updating pipeline maps.

DATES: *Effective Date:* This rule will become effective March 17, 2015.

FOR FURTHER INFORMATION CONTACT:

Damien Gaul (Technical Issues), 888 First Street NE., Washington, DC 20426, (202) 502–8008, *Damien.Gaul@ferc.gov*.

Vince Mareino (Legal Issues), 888 First Street NE., Washington, DC 20426, (202) 502–6167, *Vince.Mareino@ferc.gov*.

SUPPLEMENTARY INFORMATION:

Order No. 801

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Order No. 801

Final Rule

1. In this Final Rule, the Commission revises its part 154 regulations concerning interstate natural gas pipeline maps. First, as proposed in its Notice of Proposed Rulemaking,[1] the Commission is permanently eliminating the requirements that pipelines include system maps in their tariffs and must file to update those tariff maps by April 30 of any year following a major system change. Second, as further proposed in the NOPR, while the Commission is retaining the requirement that pipelines maintain a system map on their internet Web sites, we revise our regulations to require pipelines to update the online maps no later than the end of the next calendar quarter after a major system change. This Final Rule is designed to reduce the regulatory burden on pipelines and to enhance transparency.

I. Discussion

2. The Commission's current regulations require every natural gas interstate pipeline to maintain a system map within their tariff,[2] and specify the content of those maps and the deadline for filing updated maps.[3] Existing Commission and North American Energy Standards Board (NAESB) rules also require that pipeline system maps to be published in electronic format on the pipeline's Web site [4] as well as on the Commission's eTariff Web site. The interstate pipelines had recently informed Commission Staff, however, that certain of eTariff's file restrictions often reduce the quality of the electronic maps.[5]

3. Accordingly, the NOPR proposed to eliminate the requirement to file maps via eTariff, and instead proposed to require that pipelines provide a tariff record that contains a Web site address, or Uniform Resource Locator (URL) reference, to the pipeline's publicly available Web site where maps may be accessed.[6] The NOPR found that with the elimination of the requirement to include a map in the tariff, the current April 30 deadline to update tariff maps was effectively obsolete. The NOPR therefore proposed to revise the section 154.106 deadline for updating pipelines' internet Web site maps to require that revised maps be posted in the same calendar quarter that system changes take effect.[7]

4. Two industry segments, natural gas producers and marketers, represented by the Natural Gas Supply Association (NGSA), and the interstate pipelines, represented by the Interstate Natural Gas Association of America (INGAA), filed comments on the NOPR. Both groups generally support the Commission's proposal but suggest modifications. INGAA states that the proposed updating deadline is too strict and potentially does not allow pipelines sufficient time to post updated maps. NGSA suggests that the Commission should take this opportunity to make broad changes to modify the quality and information required for pipeline system maps.

5. As discussed below, the Final Rule implements the changes proposed in the NOPR, with the exception that we will modify the deadline for posting updated maps as proposed by INGAA so that pipelines must revise Web site maps to reflect any major change no later than the end of the calendar quarter subsequent to the calendar quarter in which the major change occurred. We also clarify how pipelines should implement the new rule, and we decline to expand the scope of this rulemaking proceeding.

[1] *Natural Gas Act Pipeline Maps,* 79 FR 43,994 (July 29, 2014), FERC Stats. & Regs. ¶ 32,703 (2014) (cross-referenced at 148 FERC ¶ 61,024 (2014)) (NOPR).

[2] 18 CFR 154.103(a) (2014).

[3] 18 CFR 154.106 (2014).

[4] *See* 18 CFR 284.12(a)(1)(v) (2014). *See also Electronic Tariff Filings,* Order No. 714, 73 FR 57,515 (Oct 3, 2008), FERC Stats. & Regs. ¶ 31,276 (2008), *clarified,* Order No. 714–A, 79 FR 29,705 (May 21, 2014) FERC Stats. & Regs. ¶ 31,356 (2014) (cross-referenced at 148 FERC ¶ 61,024 (2014) 147 FERC ¶ 61,115 (2014)).

[5] *See* NOPR, FERC Stats. & Regs. ¶ 32,703 at P 3.

[6] NOPR, FERC Stats. & Regs. ¶ 32,703 at P 5.

[7] NOPR, FERC Stats. & Regs. ¶ 32,703 at PP 6–7.

A. Implementation: 18 CFR 154.103(a) and 18 CFR 154.106(a)

6. As noted, the Commission's regulations require that natural gas pipelines' tariffs include a map of the pipeline's system.[8] The Final Rule adopts the NOPR proposal to replace this requirement to include a system map in pipelines' tariff with the requirement to include instead ''. . . a uniform resource locator for the Internet address of a map of the system . . .'' The NOPR also proposed a corresponding change to include new subsection 18 CFR 154.106(a), which we adopt here and which states that the tariff must state a uniform resource locator on the pipeline's Internet Web site, at which the general public may display and download system map(s).

7. In its comments, INGAA sought clarification regarding compliance with the proposed new rule. INGAA noted that the revised language proposed in the NOPR refers to Uniform Resource Locators, while the NOPR text refers to pipelines ''posting'' their system map on the informational posting section of their Web sites.[9] INGAA thus requests clarification that providing a 'clickable' URL in the Tariff/Map category of a pipeline's Informational Postings Web site, through which the public could view and download the pipeline's system map(s), would comply with the new regulation.[10]

8. As we stated in the NOPR, upon the adoption of this rule, NAESB should also consider whether additional standards are needed to assure accessibility and uniformity in the presentation of the maps. In the interim, we clarify that the approach proposed by INGAA, to include a URL in the Tariff/Map category of its Internet Web site, appears to be a reasonable method to for complying with revised section 154.106(a) because it would allow the public to display and download the pipeline's system map. There may be other reasonable methods for pipelines to comply based on the idiosyncrasies of a particular system, and the Commission in this Final Rule is not dictating any specific method of compliance.

B. Reporting Deadline: 18 CFR 154.106(c)

9. Under both the existing and proposed versions of 18 CFR 154.106(c), a pipeline need only update its map after a major change to its system. As noted, the existing regulation requires that the revised map be filed no later than April 30 of the calendar year after the major change, thus allowing pipelines up to 15 months to update maps from the time of a major change. The NOPR proposed to shorten that deadline to require that maps be revised to reflect any major change no later than the end of the calendar quarter of the major change.

10. INGAA commented that the reporting deadline proposed in the NOPR could require pipelines to post maps with little or no advance notice, especially if a project's in-service date is near the end of a calendar quarter. INGAA argues that this timeframe is too truncated because a pipeline's personnel are at their busiest precisely when major changes are going into effect.[11] INGAA disputes the Commission's suggestion in the NOPR that the 18 CFR 154.106 map requirement is analogous to the maps prepared as part of a NGA section 7 certificate application. The maps filed with a certificate application, INGAA states, ''very often illustrate only discrete [portions] of a pipeline system at a detailed level'' and ''are intended for different circumstances and instances'' than 18 CFR 154.106 maps.[12]

11. INGAA proposes that instead of the revisions proposed in the NOPR, the Commission should modify 18 CFR 154.106(c) to state, ''The map must be revised to reflect any major change no later than the end of the calendar quarter that immediately follows the calendar quarter in which the major change occurred.'' No interveners oppose INGAA's proposal.

12. The Final Rule adopts INGAA's proposal for section 154.106(c). The new rule will allow pipelines at least three months to update their maps, which should alleviate any concerns that pipelines will be additionally burdened during the certification process. The revised regulation will also guarantee that all maps are up-to-date within at least six months of any major changes, thereby substantially shortening the potential 15-month lag under the previous regulation.[13]

C. Scope: 18 CFR 154.106(b)

13. The NOPR proposed no changes to the language of 18 CFR 154.106(a), which specifies the required content of system maps, but did propose to move the language to 18 CFR 154.106(b). That section would state that the map must show the general geographic location of the company's principal pipeline facilities and of the points at which service is rendered under the tariff. The boundaries of any rate zones or rate areas must be shown and the areas or zones identified. The entire system should be displayed on a single map. In addition, a separate map should be provided for each zone.

14. NGSA states in its comments that ''the Commission should also use this opportunity to consider additional improvements to increase the usefulness of pipeline maps.'' [14] In particular, NGSA requests that the regulations require:

1. High resolution format to increase visibility of data.

2. Clearly labeled: Names, identification numbers, and locations of compressor stations, meter stations, receipt and delivery points, and pipeline interconnects.

3. Descriptive features, such as pipeline diameter and flow direction.[15]

15. NGSA argues that these improvements to map quality would benefit customers by gathering more visual information in one place. NGSA believes high-quality maps would also help shippers and operators, as a tool for daily operational adjustments, and for assessing capacity constraints. Finally, NGSA suggests higher-quality maps would help customers in complying with any local regulatory obligations, such as municipal taxes.[16]

16. In the NOPR, the Commission emphasized that the intent of this proceeding was to adjust the filing requirements for system maps, not to require changes to the substantive content of the maps.[17] The Commission suggested that the greater flexibility afforded by Web site posting may allow ''the overall quality of pipeline maps [to] improve without the need for prescriptive regulation,'' [18] but otherwise did not elaborate on the narrow scope of the proceeding. We find that NGSA's requests are outside the scope of this rulemaking, and thus we decline to expand the scope of this proceeding.[19]

[8] 18 CFR 154.103(a).

[9] INGAA comments at 6.

[10] *Id.*

[11] INGAA comments at 2–3.

[12] *Id.* at 4.

[13] As we clarified in the NOPR, ''[p]ipelines are also permitted to display [additional] maps showing past, future, or hypothetical operations, so long as these maps are clearly labeled as such.'' NOPR, FERC Stats. & Regs. ¶ 32,703 at P 8.

[14] NGSA comments at 2.

[15] *Id.* at 3.

[16] *Id.* at 4.

[17] NOPR, FERC Stats. & Regs. ¶ 32,703 at PP 10–11.

[18] *Id.* P 11.

[19] An agency has broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities, and may summarily deny requests to expand the scope of rulemaking proceedings. *See Wholesale Competition in Regions with Organized Electric Markets,* Order No. 719–A, FERC Stats. & Regs. ¶ 31,292, at P 118 (2009) (cross-referenced at 128 FERC ¶ 61,059, at P 118 (2009)) (citing *Chevron*

D. Effective Date

17. As the NOPR noted, this change to the map reporting requirement will obligate every natural gas pipeline to make an initial compliance filing, which as the NOPR stated, would have to be at least 90 days after the Final Rule's publication in the **Federal Register**.[20]

18. Pipelines are permitted to update their tariffs and Web sites as soon as this rule goes into effect, which will be during the first quarter of the 2015 calendar year. Because the regulation uses calendar quarters for setting deadlines, however, the Commission shall not require any pipelines to file until April 1, 2015. In this initial compliance filing, the pipeline must reference an online map updated at least through December 31, 2014.

19. Each pipeline must make its compliance filing as an eTariff filing using type of filing code (TOFC) 580, and the Commission will assign each pipeline's compliance filing a separate RP docket and provide interested parties an opportunity to intervene in those dockets. The Commission recommends that pipelines not include any other tariff changes in their eTariff compliance filing. If the content of the filing is limited to compliance with this Final Rule, then the Director of the Office of Energy Market Regulation may, pursuant to 18 CFR 375.307(a)(7)(ii), accept the filing under delegated authority.

II. Procedural Matters

A. Information Collection Statement

20. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.[21] Upon approval of a collection(s) of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

21. The Commission is submitting these reporting and recordkeeping requirements to OMB for its review and approval under section 3507(d) of the PRA. Comments are solicited on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimate, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing the respondent's burden, including the use of automated information techniques.

22. This Final Rule revises the regulations governing interstate natural gas pipeline system maps. First, the Commission eliminates the requirements that pipelines include a map in their tariffs and file an updated map as part of their tariff by the following April 30 for any year that there is a major change in the pipeline's system. Second, the Commission retains the requirement that pipelines must post and maintain a system map on their internet Web sites, and implements a quarterly deadline for updating pipeline maps.

23. The public reporting burden follows:

RM14–21–000 FINAL RULE

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
One-time tariff (Year 1)	165	1	165	8 $1,024	1,320 $168,960	$1,024
Burden Reduction (Year 2 and Beyond)	21	1	21	−4 −$244	−84 −$5,124	−$244
Additional Burden for more frequent map updates (Year 2 and Beyond)	4	1	4	4 $244	16 $976	$244
Total			190		1,252 $164,812	$1,024

24. *Title:* FERC–545, Gas Pipeline Rates: Non Formal.

Action: One-time filing and reduced future filings.

OMB Control Number: 1902–0154.

Respondents: Natural Gas Pipelines.

Frequency of Responses: One-time implementation and future reduction in number of responses. Responses are mandatory.

Necessity of Information: This Final Rule would, when implemented, reduce the burden of interstate natural gas pipelines resulting from compliance with the Commission's regulations.

Internal Review: The Commission has reviewed the requirements pertaining to the modification of the Commission's regulations and made a preliminary determination that the revisions are necessary to reduce the burden imposed by the Commission on the natural gas industry. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

Comments concerning the collection of information and the associated burden estimate, should be sent to the Commission in this docket and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, telephone: (202) 395–4638, fax: (202) 395–4718].

U.S.A. Inc. v. *NRDC,* 467 U.S. 837, 842–845 (1984)); *see also, e.g., Revisions to Page 700 of FERC Form No. 6,* Order No. 783–A, 148 FERC ¶ 61,235, at P 30 (2014).

[20] *Id.* P 12.

[21] 5 CFR 1320.11.

B. Environmental Analysis

25. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[22] The Commission has categorically excluded certain actions from these requirements as not having a significant effect on the human environment.[23] The actions taken here fall within categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for sales, exchange, and transportation of natural gas that requires no construction of facilities.[24] Therefore, an environmental assessment is unnecessary and has not been prepared as part of this Final Rule.

C. Regulatory Flexibility Act

26. The Regulatory Flexibility Act of 1980 (RFA)[25] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[26] The SBA has established a size standard for pipelines transporting natural gas stating that a firm is small if its annual receipts are less than $27.5 million.[27]

27. The changes promulgated here only impact interstate pipelines. The Commission estimates that approximately 165 entities would be potential respondents subject to data collection FERC–545 reporting requirements. Using 2013 revenue data, the Commission estimates that 70[28] pipelines not affiliated with larger companies had annual revenues of less than $27.5 million. The Commission estimates that the one-time cost per small entity is $1,024.[29] In the future, small entities should see a cost savings related to avoiding filing requirements related to system maps. The Commission does not consider the estimated $1,024 impact per entity to be significant. Accordingly, pursuant to § 605(b) of the RFA, the Commission certifies that this proposed rule should not have a significant economic impact on a substantial number of small entities.

D. Document Availability

28. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

29. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

30. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at (866) 208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

E. Effective Date and Congressional Notification

31. These regulations are effective 90 days after publication in the **Federal Register**. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of subjects in 18 CFR Part 154

Reporting and recordkeeping requirements.

By the Commission.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission shall amend Part 154, Chapter I, Title 18, *Code of Federal Regulations*, as follows:

PART 154—RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 154 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 31 U.S.C. 9701; 42 U.S.C. 7102–7352.

■ 2. Revise § 154.103(a) to read as follows:

§ 154.103 Composition of tariff.

(a) The tariff must contain sections, in the following order: A table of contents, a preliminary statement, a uniform resource locator for the Internet address of a map of the system, currently effective rates, composition of rate schedules, general terms and conditions, form of service agreement, and an index of customers.

* * * * *

■ 3. Revise § 154.106 to read as follows:

§ 154.106 Map.

(a) The tariff must state a uniform resource locator on the pipeline's Internet Web site, at which the general public may display and download system map(s).

(b) The map must show the general geographic location of the company's principal pipeline facilities and of the points at which service is rendered under the tariff. The boundaries of any rate zones or rate areas must be shown and the areas or zones identified. The entire system should be displayed on a single map. In addition, a separate map should be provided for each zone.

(c) The map must be revised to reflect any major change no later than the end of the calendar quarter that immediately follows the calendar quarter in which the major change occurred.

[FR Doc. 2014–29470 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0987]

RIN 1625–AA11

Regulated Navigation Area; Herbert C. Bonner Bridge, Oregon Inlet, NC

AGENCY: Coast Guard, DHS.

ACTION: Interim final rule; and request for comments.

SUMMARY: The Coast Guard is establishing a Regulated Navigation Area (RNA) on the navigable waters of

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[22] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897, FERC Stats. & Regs. ¶ 30,783 (1987).

[23] 18 CFR 380.4 (2014).

[24] *See* 18 CFR 380.4(a)(2)(ii), 380.4(a)(5), 380.4(a)(27) (2014).

[25] 5 U.S.C. 601–612.

[26] 13 CFR 121.101 (2013).

[27] 13 CFR 121.201, subsection 486.

[28] 42.3 percent of the total number of affected entities.

[29] *See* the Information Collection section for further explanation.

Oregon Inlet, NC surrounding the Herbert C. Bonner Bridge. This RNA will allow the Coast Guard to enforce vessel traffic restrictions within the RNA when necessary to safeguard people and vessels from the hazards associated with potential catastrophic structural damage that could occur due to vessel allisions with the bridge.

DATES: This rule is effective without actual notice on December 17, 2014. For the purposes of enforcement, actual notice will be used from November 25, 2014 until December 17, 2014.

Comments and related material must be received by the Coast Guard on or before February 17, 2015.

Requests for public meetings must be received by the Coast Guard on or before January 16, 2015.

ADDRESSES: Documents mentioned in this preamble are part of Docket Number USCG–2014–0987. 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.

You may submit comments, identified by docket number, using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* (202) 493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

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 Derek Burrill, Waterways Management Division Chief, U.S. Coast Guard Sector North Carolina, telephone (910) 772–2230, email *Derek.J.Burrill@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

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
RNA Regulated Navigation Area

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, 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, 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 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 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

We do not now plan to hold a public meeting. But you may submit a request for one on or before January 16, 2015, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

The Coast Guard is issuing this interim final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.''

Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. Immediate action is necessary to protect the maritime public who transit Oregon Inlet and motorists that use the Herbert C. Bonner bridge. Vessel strikes to the Herbert C. Bonner Bridge could cause catastrophic damage to the bridge makes immediate action necessary to minimize the risk of potential loss of life, damage to the bridge, and the impact on access to Hatteras Island. Accordingly, waiting for a comment

period to run is impractical as it would expose the public to a longer danger period.

The particular facts about the Bonner Bridge and the waterway require special vessel traffic control measures. A bridge strike by a vessel could cause catastrophic damage to the bridge, impacting motorists, mariners, local businesses and residents of Hatteras Island, NC. The North Carolina Department of Transportation (NC DOT) indicates that the Bonner Bridge has a very low sufficiency rating. Sufficiency rating is an overall rating of a bridge's fitness for the duty that it performs. In addition, recent hydrographic survey data reports indicate shoaling is present in the vicinity of the navigation span. When such shoaling is present, the Coast Guard has observed vessels attempting to transit through alternate spans of the Herbert C. Bonner Bridge. Transiting through alternate spans is hazardous as they are not intended for navigation. The un-fendered or unprotected structural components of the bridge among these spans are more vulnerable to damage caused by a vessel strike, increasing the risk of consequent catastrophic damage.

For the same reasons as discussed about, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

C. Basis and Purpose

This rulemaking is authorized by 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; and DHS Delegation No. 0170.1. Under these authorities the Coast Guard may establish an RNA in defined water areas that are determined to have hazardous conditions and in which vessel traffic can be regulated in the interest of safety. The purpose of this RNA is to reduce the risk of a bridge strike resulting from a vessel transiting through alternative spans of the Herbert C. Bonner Bridge, which are not intended for navigation. A bridge strike to un-fendered or unprotected structural elements of the Bonner Bridge would introduce a clear and present danger to stability of the bridge, motorists, mariners, and indirect impacts on local businesses and residents of Hatteras Island, NC.

U.S. Army Corps of Engineers (USACE) hydrographic survey data provide to the Coast Guard over the past two years indicates shoaling to depths of less than 3 feet at mean low water within the approaches to the Bonner Bridge on a frequently occurring basis. When shoaling is present in the vicinity of the navigation span, vessels attempt to transit through alternate spans. Transiting through alternate spans is hazardous. Mariners transiting near and through the unprotected structural components increase the potential of a bridge strike; these spans do not have fenders or other mechanisms to protect the bridge from vessel strikes. Vessels that transit alternate bridge spans risk safe navigation as there are no advertised vertical and horizontal clearances in these areas.

The Coast Guard has also considered the North Carolina Department of Transportation (NC DOT) recent biennial bridge inspection in accordance with National Bridge Inspection Standards (NBIS) for the Herbert C. Bonner Bridge. This report takes into account the substructure and superstructure inspections along with analysis of the maritime navigational and motor vehicle concerns. The report noted weakened pile supports as a result of section loss and substructure erosion to the point of showing exposed rebar. Information provided to the Coast Guard by NC DOT indicates that the Herbert C. Bonner Bridge has a very low sufficiency rating. Due to the dynamic nature of Oregon Inlet waterway, frequent dredging and realignment of the approach channel east of the bridge have become routine. Passage of hurricanes and strong low pressure systems, *i.e.* Nor'easters exacerbate tidal current and the seasonal fluctuations of the inlet's water depths. Maintenance of adequate depth and adequate channel alignment is a temporary measure that typically provides for safe vessel navigation for a very limited time period for safe vessel navigation. Maintenance dredging of the Federal Navigation Project is dependent on available funding, marine weather dredging windows, and channel condition surveys. Because many of these factors are uncontrollable, dredging operations are not regularly scheduled maintenance activities.

The Herbert C. Bonner Bridge is the only vehicular access to Hatteras Island for residents, commercial vendors, and business owners transiting from Nags Head-Bodie Island to Hatteras Island. The Bonner Bridge is subject to heavy traffic volume, particularly during the summer tourist season. Risks to the lives of mariners, vehicle motorist and passengers, have been considered in the development of this rulemaking.

D. Discussion of the Interim Rule

To address the aforementioned hazards, this rule will establish restrictions for the Oregon Inlet waterway by prohibiting vessels with certain characteristics from transiting under or within 100 yards either side of the Herbert C. Bonner Bridge. The Coast Guard invites comments and will consider comments in development of a final regulation. This RNA will be effective with actual notice for purposes of enforcement on November 25, 2014. The restrictions for navigation will be enforceable 24 hours a day as long as this RNA is in effect. The Coast Guard will enforce the restriction, however, only when necessary to protect people and vessels from hazards. As indicated above, the Coast Guard expects to restrict marine traffic if there is shoaling that impacts safe vessel transit through the navigation span, or there is damage to the bridge that presents a hazard to people and vessels.

There are alternate routes for vessels bound for Oregon Inlet, North Carolina and inland waterfront communities, including Wanchese, NC. Those alternate routes include transiting through Beaufort Inlet or Chesapeake Bay and the Atlantic Intracoastal Waterway and Sounds of North Carolina. The distance from Oregon Inlet Lighted Whistle Buoy ''OI'' to Wanchese, North Carolina via Beaufort Inlet, the Atlantic Intracoastal Waterway and Pamlico Sound is approximately 190 nautical miles. The distance from Oregon Inlet Lighted Whistle Buoy ''OI'' to Wanchese, North Carolina via Chesapeake Bay, the Atlantic Intracoastal Waterway and Albemarle Sound is approximately 200 nautical miles.

Whenever it is determined that a waterway restriction for Oregon Inlet is necessary, the Coast Guard will provide the public with as much advanced notice as possible of the closure dates and times. Such notice will be readily provided via *http://homeport.uscg.mil/,* Local Notice to Mariners, Broadcast Notice to Mariners, and other methods described in 33 CFR 165.7.

E. 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.

This regulation will restrict access within the Regulated Navigation Area at Oregon Inlet and the Herbert C. Bonner Bridge, the effect of this rule will not be significant because: (i) The Coast Guard will make extensive notifications of the regulated area to the maritime public via maritime advisories so mariners can adjust their plans accordingly; and (ii) vessels impacted by this regulation may request permission from Commander Coast Guard Sector North Carolina/ COTP North Carolina to transit the regulated area on a case by case basis.

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 Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. The regulation may have an economic impact on vessels that normally transit Oregon Inlet. These small entities are primarily commercial and recreational fishing vessels. Operation of vessels of certain characteristics in this RNA will be prohibited from transiting Oregon Inlet by the Captain of the Port (COTP) or designated representative when shoaling in the vicinity of the Herbert C. Bonner Bridge creates unsafe condition for vessels. The potential risk of loss of life, damage to the bridge, and the impact on access to Hatteras Island outweighs the benefits of permitting navigation in the vicinity or under the Bonner Bridge.

Although the Oregon Inlet area is used by many small entities, including commercial and recreational fishing businesses, alternate routes are available to vessels. The Coast Guard will make extensive notifications of the regulated navigation area to the maritime public via maritime advisories so mariners can adjust their plans accordingly; and in extreme circumstances, vessels prohibited from entry may request permission from Commander Coast Guard Sector North Carolina/COTP North Carolina to transit the RNA on a case by case basis.

3. Assistance for Small Entities

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

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

4. Collection of Information

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

5. Federalism

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

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and 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

establishment of a Regulated Navigation Area. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. Preliminary environmental analysis checklist supporting this determination and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS.

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

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

■ 2. Add § 165.520 to read as follows:

§ 165.520 Regulated Navigation Area; Herbert C. Bonner Bridge, Oregon Inlet, NC.

(a) *Regulated area.* The following area is a Regulated Navigation Area (RNA): All navigable waters of Oregon Inlet, North Carolina within 100 yards under or surrounding any portion of the Herbert C. Bonner Bridge.

(b) *Definitions.* As used in this section:

(1) *Captain of the Port* means the Captain of the Port (COTP) North Carolina.

(2) *Captain of the Port Representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port North Carolina to act as a designated representative of the COTP.

(3) *Official patrol vessel* means any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessel(s) assigned and authorized by COTP North Carolina.

(c) *Regulations.* (1) The general regulations governing Regulated Navigation Areas found in 33 CFR 165.10, 165.11, and 165.13, including the Regulated Navigation Area described in paragraph (a) of this section and the following regulations, apply.

(2) Operation of vessels of certain characteristics in this RNA will be prohibited by the Captain of the Port (COTP) or designated representative in order to safeguard people and vessels from the hazards associated with shoaling and the Herbert C. Bonner Bridge from the potential catastrophic structural damage that could occur from a vessel bridge strike. The COTP or designated representative will evaluate local marine environmental conditions prior to issuing restrictions regarding vessel navigation. Factors that will be considered include, but are not limited to: Hydrographic survey data, vessel characteristics such as displacement, tonnage, length and draft, current weather conditions including visibility, wind, sea state, and tidal currents.

(3) The Coast Guard will notify the public of restrictions via Local Notice to Mariners, Broadcast Notice to Mariners, and via other methods described in 33 CFR 165.7. Additionally, Coast Guard personnel may be on-scene to advise the public of enforcement of any restrictions on vessel navigation within the RNA.

(4) In accordance with the general regulations, entry into, anchoring, or movement within the RNA, during periods of enforcement, is prohibited unless authorized by the Captain of the Port (COTP) or the COTP's on-scene designated representative. The ''on-scene designated representative'' of the COTP is any Coast Guard commissioned, warrant or petty officer who has been designated by the COTP to act on the COTP's behalf. The on-scene representative may be on a Coast Guard vessel; State agency vessel, or other designated craft; or may be on shore and will communicate with vessels via VHF–FM marine band radio or loudhailer. Members of the Coast Guard Auxiliary may be present to assist COTP representatives with notification of vessel operators regarding the contents of this regulation.

(5) Any deviation from paragraph (c)(4) of this section due to extreme circumstances must be authorized by the Coast Guard District Commander, the Captain of the Port (COTP) or the COTP's designated representative. Vessels granted permission to transit the RNA must do so in accordance with the directions provided by the COTP or COTP representative to that vessel. To request permission to transit the regulated navigation area, the COTP or COTP representative can be contacted at Coast Guard Sector North Carolina, telephone number (910) 343–3880, or on VHF–FM marine band radio channel 13 (165.65MHz) or channel 16 (156.8 MHz). During periods of enforcement, all persons and vessels given permission to enter or transit within the RNA must comply with the instructions of the COTP or designated representative. Upon being hailed by an official patrol vessel by siren, radio, flashing-light, or other means, the operator of a vessel must proceed as directed.

(d) *Enforcement.* The Coast Guard may be assisted in the patrol and enforcement of the Regulated Navigation Area by other Federal, State, and local agencies. The COTP may impose additional requirements within the RNA due to unforeseen changes to shoaling of Oregon Inlet or structural integrity of the Herbert C. Bonner Bridge.

(e) *Notification.* The Coast Guard will rely on the methods described in 33 CFR 165.7 to notify the public of the date, time and duration of any closure of the RNA. Violations of this RNA may be reported to the COTP at (910) 343–3880 or on VHF–FM channel 16.

Dated: November 25, 2014.

Stephen P. Metruck,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2014–29589 Filed 12–16–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2013–0040]

RIN 1625–AA87

Revision of Safety/Security Zone Regulations; 2014 Tampa Bay; Captain of the Port St. Petersburg Zone, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is consolidating three security zone regulations into one regulation. In addition, the Coast Guard is disestablishing two safety zone regulations and converting those safety zones into security zones for all navigable waterways of Big Bend, Boca Grande, Crystal River, East Bay, Hillsborough Bay, MacDill Air Force Base, Manbirtee Key, Old Port Tampa, Port Manatee, Port Tampa, Port St. Petersburg, Port Sutton, Rattlesnake, and Weedon Island, FL. The purpose of these revisions is to ensure the security of vessels, facilities, and the surrounding areas within these zones. Entry into the area encompassed by these security zones is prohibited without permission of the Captain of the Port St. Petersburg or a designated representative.

DATES: This rule is effective December 17, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2013–0040. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Marine Science Technician First Class Hector I. Fuentes, Sector Saint Petersburg Waterways Management Branch, U.S. Coast Guard; telephone (813) 228–2191, email *Hector.I.Fuentes@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. Regulatory History and Information

On September 15, 2014, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled, ''Revision of Safety/Security Zone Regulations; 2014 Tampa Bay; Captain of the Port St. Petersburg Zone, FL'' in the **Federal Register** (79 FR 54937). We received no comments on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Due to the inherent dangers involved with the transport of the hazardous cargos included in this rule, it is in the best interest of the public to have a regulation in place and to not delay its effective date.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish limited access areas: 33 U.S.C.1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1. The purpose of the regulation is to reorganize and consolidate three existing security zones in 33 CFR 165.760, 33 CFR 165.767 and 33 CFR 165.768 into a single regulation and to combine the safety zones in 33 CFR 165.703 and 33 CFR 165.704 into a single security zone regulation to ensure the security of vessels, facilities, and the surrounding areas and provide safety of life on the navigable waters in the Captain of the Port St. Petersburg Zone.

C. Comments, Changes and the Final Rule

There were no comments related to this regulation during the comment period and there was no request for a public meeting made during the comment period.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders. These regulations were routed through and approved by the Tampa Bay Harbor Safety and Security Committee.

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.

This regulation is not a significant regulatory action because this change constitutes merely the merging of and increased size of existing regulations. This rule may have some impact on the public, but these potential impacts will be minimized for the following reasons: There is ample room for vessels to navigate around security zones and there are several locations for recreational and commercial fishing vessels to fish throughout the Tampa Bay region.

Also, vessels wishing to enter, transit through, or anchor in the regulated areas may do so with the permission of the Captain of the Port.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. 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 would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.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 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 is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Revise § 165.703 to read as follows:

§ 165.703 Security Zones; Tampa Bay: Big Bend, Boca Grande, Crystal River, East Bay, Hillsborough Bay, MacDill Air Force Base, Manbirtee Key, Old Port Tampa, Port Manatee, Port Tampa, Port St. Petersburg, Port Sutton, Rattlesnake, and Weedon Island, FL.

(a) *Regulated areas.* The following areas, denoted by coordinates fixed using the North American Datum of 1983 (World Geodetic System 1984) are security zones:

(1) *Security zones for facilities and structures*—(i) *Rattlesnake, Tampa, FL.* All water, from surface to bottom, in Old Tampa Bay east and south of the waters encompassed within position 27°53.32′ N, 082°32.05′ W; thence to 27°53.38′ N, 082°32.05′ W, including on land portions of Chemical Formulators Chlorine Facility, where the fenced area is bounded by a line connecting the following points: 27°53.21′ N, 082°32.11′ W; thence to 27°53.22′ N, 082°32.23′ W; thence to 27°53.25′ N, 082°32.23′ W; thence to 27°53.25′ N, 082°32.27′ W; thence to 27°53.29′ N, 82°32.25′ W; thence to 27°53.30′ N, 082°32.16′ W; thence to 27°53.21′ N, 082°32.11′ W.

(ii) *Old Port Tampa, Tampa, FL.* All waters, from surface to bottom, in Old Tampa Bay encompassed within the following points: 27°51.62′ N, 082°33.14′ W; thence to 27°51.71′ N, 082°32.5′ W; thence to 27°51.76′ N, 082°32.5′ W; thence to 27°51.73′ N, 082°33.16′ W; thence to 27°51.62′ N, 082°33.14′ W, closing off the Old Port Tampa Channel.

(iii) *Sunshine Skyway Bridge, FL.* All waters in Tampa Bay, from surface to bottom, in Cut ''A'' channel beneath the bridge's main span encompassed within the following points: 27°37.30′ N, 082°39.38′ W; 27°37.13′ N, 082°39.26′ W; and the bridge structure columns, base and dolphins. This zone is specific to the bridge structure and dolphins and does not include waters adjacent to the bridge columns or dolphins outside of the bridge's main span. Any vessel may transit through this zone but, may not loiter, anchor, or conduct operations, including dredging, dive operation, surveying, or maintenance, unless otherwise directed by the Captain of the Port. Anyone wanting to conduct these operations must submit a request via email to *WWMTampa@uscg.mil* or contact the Sector Command Center after hours at 727.824.7506.

(iv) *Manbirtee Key, Port of Manatee, FL.* All waters, from surface to bottom, surrounding, surrounding Manbirtee Key, Tampa Bay, FL extending 500 yards from the island's shoreline, in all directions, not to include the Port Manatee Channel.

(v) *MacDill Air Force Base, Tampa Bay, FL.* All waters encompassed within the following coordinates: 27°51.88′ N, 082°29.31′ W; thence to 27°52.01′ N, 082°28.85′ W; thence to 27°51.48′ N, 082°28.17′ W; thence to 27°51.02′ N, 082°27.76′ W; thence to 27°50.72′ N, 082°27.61′ W; thence to 27°50.33′ N, 082°27.59′ W; thence to 27°49.65′ N, 082°27.73′ W; thence to 27°49.34′ N, 082°27.79′ W; thence to 27°49.10′ N, 082°27.88′ W; thence to 27°48.88′ N, 082°28.10′ W; thence to 27°48.76′ N, 082°28.54′ W; thence to 27°48.87′ N, 082°29.44′ W; thence to 27°49.06′ N, 082°30.39′ W; thence to 27°48.75′ N, 082°31.17′ W; thence to 27°49.16′ N, 082°32.41′ W; thence to 27°49.64′ N, 082°33.04′ W; thence to 27°49.95′ N, 082°32.75′ W; thence to 27°50.09′ N, 082°32.81′ W; thence to 27°50.56′ N, 082°32.75′ W; thence to 27°50.71′ N, 082°32.18′ W.

(vi) *Piers, seawalls, and facilities, Port of Tampa and Port Sutton, Tampa, FL.* All waters, from surface to bottom, extending 50 yards from the shore, seawall, and piers around facilities in Port Sutton within the Port of Tampa encompassed by a line connecting the following points: 27°54.15′ N, 082°26.06′ W; thence to; 27°54.46′ N, 082°25.71′ W; closing off all Port Sutton Channel.

(vii) *Piers, seawalls, and facilities, Port of Tampa, on the western side of*

Hooker's Point, Tampa, FL. All waters, from surface to bottom, extending 50 yards from the shore, seawall, and piers around facilities on Hillsborough Bay northern portion of Cut ''D'' Channel, Sparkman Channel, Ybor Turning Basin, and Ybor Channel within the Port of Tampa encompassed by a line connecting the following points: 27°54.74′ N, 082°26.47′ W; thence to 27°55.25′ N, 082°26.73′ W; thence to 27°55.60′ N, 082°26.80′ W; thence to 27°56.00′ N, 082°26.75′ W; thence to 27°56.58′ N, 082°26.53′ W; thence to 27°57.29′ N, 082°26.51′ W; thence to 27°57.29′ N, 082°26.61′ W; thence to 27°56.65′ N, 082°26.63′ W; thence to 27°56.58′ N, 082°26.69′ W; thence to 27°56.53′ N, 082°26.90′ W.

(viii) *St. Petersburg Harbor, FL.* All waters, from surface to bottom, extending 50 yards from the seawall and around all moorings and vessels in St. Petersburg Harbor (Bayboro Harbor), commencing on the north side of the channel at day beacon ''10'' (LLNR 24995) in approximate position 27°45.56′ N, 082°37.55′ W, and westward along the seawall to the end of the cruise terminal in approximate position 27°45.72′ N, 082°37.97′ W. The zone will also include the Coast Guard south moorings in St. Petersburg Harbor. The zone will extend 50 yards around the piers commencing from approximate position 27°45.51′ N, 082°37.99′ W; to 27°45.52′ N, 082°37.57′ W. The southern boundary of the zone is shoreward of a line between the entrance to Salt Creek easterly towards day beacon ''11'' (LLNR 24990).

(ix) *Crystal River Nuclear Power Plant.* All waters, from surface to bottom, around the FL, Power Crystal River Nuclear Power Plant located at the end of the Florida Power Corporation Channel, Crystal River, Florida, encompassed by a line connecting the following points: 28°56.87′ N, 082°45.17′ W; thence to 28°57.37′ N, 082°41.92′ W; thence to 28°56.79′ N, 082°45.13′ W; thence to 28°57.32′ N, 082°41.92′ W.

(x) *Crystal River Demory Gap Channel.* All waters, from surface to bottom, in the Demory Gap Channel in Crystal River, Florida, encompassed by the following points: 28°57.61′ N, 082°43.42′ W thence to; 28°57.55′ N, 082°41.88′ W thence to; 28°57.58′ N, 082°43.42′ W thence to; 28°57.51′ N, 082°41.88′ W.

(xi) *Big Bend Power Plant, FL.* All waters of Tampa Bay, from surface to bottom, adjacent to the Big Bend Power Facility, and within an area bounded by the following points: 27°48.08′ N, 082°24.88′ W; thence to 27°48.15′ N, 082°24.96′ W; thence to; 27°48.10′ N, 082°25.00′ W; thence to 27°47.85′ N, 082°25.03′ W; thence to 27°47.58′ N, 082°24.89′ W; thence to 27°47.58′ N, 082°24.06′ W; thence to; 27°47.62′ N, 082°24.04′ W; thence to 27°47.63′ N, 082°24.71′ W; thence to 27°48.03′ N, 082°24.70′ W; thence to 27°48.08′ N, 082°24.88′ W, closing off entrance to Big Bend Power Facility and the attached cooling canal.

(xii) *Weedon Island Power Plant, FL.* All waters of Tampa Bay, from surface to bottom, extending 50 yards from the shore, seawall and piers around the Power Facility at Weedon Island encompassed by the following points: 27°51.52′ N, 082°35.82′ W; thence along the shore to; 27°51.54′ N, 082°35.78′ W; thence to 27°51.89′ N, 082°35.82′ W; thence to 27°51.89′ N, 082°36.14′ W, closing off the entrance to both canals.

(2) *Vessel specific security zones*—(i) *Moving security zones for Cruise Ships and vessels carrying Especially Hazardous Cargos.* The following security zones and procedures are established for all waters, from surface to bottom, within a 500-yard radius, as outlined below:

(A) For inbound vessels commencing at Egmont Channel Lighted Buoys ''9'' (LLNR 22270) and ''10'' (LLNR 22275) through to berth.

(B) For shifting vessels from their departure berth to destination berth.

(C) For outbound vessels commencing at berth through to Egmont Channel Lighted Buoys ''9'' (LLNR 22270) and ''10'' (LLNR 22275).

(D) All subject vessels operating in the Captain of the Port St. Petersburg Zone shall follow the reporting requirements in 33 CFR part 160, subpart C.

(E) Any vessel desiring to enter or transit the security zone shall obtain permission from the Captain of the Port St. Petersburg or a designated representative. If permission is granted, all persons and vessels must comply with any given instructions.

(ii) *Fixed security zones for moored cruise ships and moored vessels carrying especially hazardous cargos.* A security zone is established for all waters, from surface to bottom, within a 200-yard radius around moored cruise ships and moored vessels carrying especially hazardous cargos, as outlined below:

(A) All subject vessels operating in the Captain of the Port St. Petersburg Zone shall follow reporting requirements in 33 CFR part 160, subpart C.

(B) Any vessel desiring to enter or transit the security zone shall obtain permission from the Captain of the Port St. Petersburg or a designated representative. If permission is granted, all persons and vessels must comply with any given instructions.

(C) No vessel may loiter, anchor, or conduct maintenance operations within the security zone, unless otherwise directed by the Captain of the Port St. Petersburg or a designated representative. This includes, but is not limited to dredging operations, dive operations, and surveying. Anyone wanting to conduct these operations must submit a request via email to *WWMTampa@uscg.mil* or contact the Sector Command Center after hours at 727.824.7506.

(b) *Definitions.* As used in this section:

Ammonium nitrate means ammonium nitrate and ammonium nitrate based fertilizers listed as Division 5.1 (oxidizing) materials as defined in 33 CFR 172.101 except when carried as CDC residue.

Captain of the Port (COTP) for the purpose of this section means the Commanding Officer of Coast Guard Sector St. Petersburg.

Captain of the Port St. Petersburg Zone as defined in 33 CFR 3.35–35.

Commercial vessels means any tank, bulk, container, cargo, cruise ships, pilot vessels, or tugs. This definition excludes fishing vessels, salvage vessels, dead ship tow operations.

Cruise Ship means the same as defined 33 CFR 101.105.

Designated representative means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and federal, state, and local officers designated by or assisting the COTP, in the enforcement of regulated navigation areas, safety zones, and security zones.

Certain dangerous cargo includes *Division 1.5D* blasting agents for which a permit is required under 49 CFR 176.415 or, for which a permit is required as a condition of Research and Special Programs Administration exemption. This includes ammonium nitrate fuel oil mixture.

Especially hazardous cargo means anhydrous ammonia, ammonium nitrate, chlorine, liquefied natural gas, liquefied petroleum gas, and any other substance, material, or group or class in a particular amount and form that the Secretary determines by regulation poses a significant risk of creating a transportation security incident while being transported in maritime commerce.

(c) *Regulations.* (1) Entry into or remaining on or within the zones described in paragraph (a) of this section is prohibited unless authorized

by the Captain of the Port St. Petersburg or a designated representative.

(2) Any changes to the requirements for these regulated areas will be given by Broadcast Notice to Mariners on VHF–FM Channel 22A.

Note to § 165.703(c)(2): A graphical representation of all fixed security zones will be made available through nautical charts via the Coast Pilot.

(3) The Captain of Port St. Petersburg has provisions for escorting especially hazardous cargos as described in the above sections of this subchapter, but reserves the right to establish additional provisions for any potentially hazardous cargos.

(4) *Enforcement.* Under 33 CFR 165.33, no person may authorize the operation of a vessel in the security zones contrary to the provisions of this section.

(d) The Captain of the Port St. Petersburg may waive any of the requirements of this subpart for any vessel, facility, or structure upon finding that the vessel or class of vessel, operational conditions, or other circumstances are such that application of this subpart is unnecessary or impractical for purposes of port safety and security or environmental safety.

§§ 165.704, 165.760, 165.767, and 165.768 [Removed and Reserved]

■ 3. Remove and reserve §§ 165.704, 165.760, 165.767, and 165.768.

Dated: November 20, 2014.

G. D. Case,

Captain, U.S. Coast Guard, Captain of the Port St. Petersburg.

[FR Doc. 2014–29582 Filed 12–16–14; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

New Standards To Enhance Business Reply Mail (BRM) Visibility

AGENCY: Postal Service.™

ACTION: Final rule.

SUMMARY: The Postal Service™ will revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to require the use of an Intelligent Mail® package barcode (IMpb) on Business Reply Mail® (BRM) labels intended for use on cartons, parcel-shaped items, or Priority Mail® items of any shape.

DATES: *Effective date:* April 30, 2015.

FOR FURTHER INFORMATION CONTACT: Juliaann Hess at 202–268–7663, John F. Rosato at 202–268–8597, or Suzanne Newman at 202–695–0550.

SUPPLEMENTARY INFORMATION:

I. Proposed Rule

The Postal Service published a proposed rule (79 FR 4871) on August 18, 2014, with a comment period ending September 17, 2014, to enhance its operational capability to scan IMpbs and to provide tracking information to mailers by requiring a unique IMpb on cartons, parcel-shaped items, or Priority Mail pieces of any shape, returned using BRM service. Full implementation of the Postal Service's package visibility strategy relies on the availability of piece-level information provided through the widespread use of IMpb. Mailing standards recently added to the DMM now require the use of IMpb on all commercial parcels (except parcels paid for using BRM service). Therefore, this change will align the IMpb standards for BRM parcels with that of all other commercial parcels, Merchandise Return Service (MRS) including USPS Returns, and Parcel Return Service.

Background: On December 18, 2013, the Postal Service published a final rule in the **Federal Register** (78 FR 76548) announcing that an IMpb, unique to each mailpiece, would be required on all commercial parcels, effective January 26, 2014. At that time the Postal Service also announced that it would be eliminating the option for any mailpiece meeting the physical characteristics of a parcel (under DMM 201), or Priority Mail pieces of any shape, to pay for postage using Business Reply Mail® (BRM).

In response to mailer feedback, on June 5, 2014, the Postal Service published a **Federal Register** document (79 FR 32490) indefinitely deferring the elimination of the option to use BRM to pay postage for cartons, parcel-shaped items, or Priority Mail pieces of any shape. At that time the Postal Service also indicated that it expected to issue proposed rules requiring the use of an IMpb on certain BRM cartons and labels.

In accordance with its previously expressed intent, the Postal Service published the proposed rule, on August 18, 2014, for requiring the use of an IMpb on BRM cartons, parcels, and Priority Mail items of any shape.

General IMpb Requirements: Technical and general specifications for IMpb use are provided in Publication 199, *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Verification System (eVS) Mailers,* and DMM 708.5.1.

BRM: In order to ensure that parcel-shaped items returned using BRM service comply with the same standards as all other commercial parcels including returns, the Postal Service will require a unique IMpb on:

a. All BRM cartons.

b. All BRM labels distributed with the intent of being placed on an item meeting the physical characteristics of a parcel in DMM 201.

c. All BRM labels distributed with the intent of being placed on Priority Mail items of any shape.

For the purposes of this requirement, a BRM carton is defined as a parcel-shaped mailpiece with a BRM label either printed directly on the mailpiece or affixed by the end user prior to mailing. BRM permit holders would not be required to submit shipping manifests to support these mailpieces. BRM labels would be required to use a unique Mailer ID (MID) for parcel-shaped BRM pieces and a concatenated IMpb construct that includes the ZIP+4® routing code. The barcodes must be unique for 180 days. BRM cartons and parcels will use the same IMpb service type codes used for Merchandise Return Service (MRS), for Priority Mail, or for First-Class Mail®, based on the product used. The Postal Service provides an exception process—for mailers of small BRM cartons and parcels lacking sufficient label space to apply an IMpb barcode meeting the ¾-inch height requirement—to submit barcodes of at least ½-inch in height for USPS® testing and approval. This exception process will be administered by the National Customer Service Center (NCSC), as part of the routine package barcode approval process. At this time, no other changes are being made to BRM standards under DMM 505.1 as applicable to all other mail shapes.

Noncompliant Mailpieces: Once this final rule becomes effective, the Postal Service will assess a per-piece IMpb non-compliance fee on all BRM parcels not bearing an IMpb and returned using Priority Mail service. The proposed effective date for the per-piece IMpb non-compliance fee on First-Class Mail parcels being returned using BRM would be predicated on the Postal Service filing a notice with, and receiving approval from, the Postal Regulatory Commission. Thus, the non-compliance fee would start immediately with Priority Mail pieces only.

II. Comments and Responses

The Postal Service received one comment to the proposed rule of August, 18, 2014, from a Postal Service employee. The employee commented on the barcoding resources available for small to mid-size mailers and the use of Label 400 with BRM parcels. The Postal

Service continues to encourage mailers to use one of the various merchandise return services products for return merchandise, instead of using Business Reply Mail, which is primarily intended for use with letter and flat sized pieces. The Postal Service currently offers a Merchandise Return Service (MRS) web-tool (API) interface that permits all mailers to create their MRS labels with the required IMpb. The Postal Service will continue to consider additional enhancements for all return services to make it easier for companies of all sizes to do business with us.

III. Features of the Final Rule

The Postal Service continues to enhance its operational capability to scan IMpbs, encoded with routing and tracking information, via automated mail processing equipment and Intelligent Mail scanning devices, and to provide tracking information to the mailers. Full implementation of the Postal Service's package visibility strategy relies on the availability of piece-level information provided through the widespread use of IMpb.

Recent changes to mailing standards now require the use of IMpb on all commercial parcels (excluding parcels paid for using BRM service). The Postal Service now advances its package visibility strategy by requiring a unique IMpb on cartons, parcels, or Priority Mail pieces of any shape, preprinted or with labels affixed to be returned using BRM service.

For the purposes of this requirement, a BRM carton is defined as a parcel-shaped mailpiece with a BRM label either printed directly on the mailpiece or affixed by the end user prior to mailing. BRM permit holders would not be required to submit shipping manifests to support these mailpieces. BRM labels would be required to use a unique Mailer ID (MID) for BRM parcels and a concatenated IMpb construct that includes the ZIP+4®routing code. The barcodes must be unique for 180 days. BRM cartons and parcels will use IMpb service type codes for Merchandise Return Service for Priority Mail or First-Class Mail®, based on the product used. The Postal Service will provide an exception process—for mailers of small BRM cartons and parcels lacking sufficient label space to apply an IMpb barcode meeting the ¾-inch height requirement—to submit barcodes of at least ½-inch in height for USPS testing and approval. This exception process will be administered by the National Customer Service Center (NCSC), as part of the normal package barcode approval process. At this time, no other changes would be made to the BRM standards in DMM 505.1 applicable to all other mail shapes.

Noncompliant Mailpieces: The Postal Service will assess a per-piece IMpb non-compliance fee on all BRM parcels not bearing an IMpb and returned using Priority Mail. The proposed effective date for the per-piece fee on First-Class Mail parcels being returns using BRM would be predicated on the Postal Service filing a notice with, and receiving approval from, the Postal Regulatory Commission. Thus, the non-compliance fee starts immediately with Priority Mail pieces only.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

For the reasons stated in the preamble, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

505 Return Services

1.0 Business Reply Mail (BRM)

* * * * *

1.4 General Information

1.4.1 Description

[Insert a new fourth sentence in 1.4.1 to read as follows:]

* * * All BRM labels intended for use on cartons, mailpieces meeting the physical characteristics of a parcel in DMM 201, or a Priority Mail item of any shape, must meet the standards under 1.7.10.

* * *

* * * * *

1.7 Mailpiece Characteristics

* * * * *

[Insert new 1.7.10 to read as follows:]

1.7.10 Labels for Parcels

BRM labels intended for use on cartons, mailpieces meeting the physical standards of a parcel under DMM 201, or a Priority Mail item of any shape, must also bear an IMpb prepared under 708.5.0 and meet the technical standards in the Parcel Labeling Guide available on RIBBS.

* * * * *

1.8 Format Elements

1.8.1 General

[Revise the text of the first and second sentences of 1.8.1 to read as follows:] Except for BRM labels for parcels as provided under 1.7.10, all pieces of BRM are subject to these format elements. For all other BRM pieces, an Intelligent Mail barcode (IMb) is not required, except for QBRM prices; if an IMb is used, it must be printed and placed as provided under 1.9 and as shown in Exhibit 1.8.1. * * *

* * * * *

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2014–29479 Filed 12–16–14; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0662; FRL–9918–99]

Fluopyram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluopyram in or on multiple commodities that are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 17, 2014, except for the amendment to § 180.661 in amendatory instruction number 3, which is effective June 17, 2015. Objections and requests for hearings must be received on or before February 17, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0662, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room

is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2013–0662 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 17, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0662, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2014 (79 FR 29729) (FRL–9910–29), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8190) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.661 be amended by establishing tolerances for residues of the fungicide fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, including its metabolites and degradates in or on the following commodities: Beef, byproducts at 0.70 parts per million (ppm); beef, fat at 0.10 ppm; beef, meat at 0.10 ppm; grain, cereal, forage, group 16 at 1.5 ppm; cotton, gin by-products at 0.80 ppm; cotton, seed at 0.01 ppm; egg at 0.15 ppm; grain, cereal group 15, except rice at 0.03 ppm; grain, cereal, fodder, hay and straw, group 16 at 2.0 ppm; hog, fat at 0.05 ppm; hog, meat at 0.10 ppm; hog, meat byproducts at 0.70 ppm; milk at 0.10 ppm; peanuts at 0.09 ppm; poultry, fat at 0.10 ppm; poultry, meat at 0.10 ppm; poultry, meat byproducts at 0.20 ppm; and soybean, seed at 0.04 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is issuing some tolerances that vary from the fluopyram tolerances as requested. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopyram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopyram 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.

Decreased body weight and liver effects were the common and frequent findings in the fluopyram subchronic and chronic oral toxicity studies in rats, mice, and dogs, and they appeared to be the most sensitive effects. Liver effects were characterized by increased liver weight, hepatocellular hypertrophy, hepatocellular vacuolation, increased mitosis and hepatocellular necrosis. Thyroid effects were found at dose levels similar to those that produced liver effects in rats and mice; these effects consisted of follicular cell hypertrophy, increased thyroid weight and hyperplasia at dose levels greater than or equal to 100 milligrams/kilogram/day (mg/kg/day). Changes in thyroid hormone levels were also seen in a subchronic toxicity study. In male mice, there was an increased incidence of thyroid adenomas.

Although increased liver tumors were observed in female rats in the carcinogenicity study, EPA has concluded that fluopyram is ''Not Likely to be Carcinogenic to Humans'' at doses that do not induce cellular proliferation in the liver or thyroid glands. This classification was based on convincing evidence that non-genotoxic modes of action for liver tumors in rats and thyroid tumors in mice have been established and that the carcinogenic effects have been demonstrated as a result of a mode of action dependent on activation of the CAR/PXR receptors. Moreover, fluopyram is not genotoxic or mutagenic.

Fluopyram is not a developmental toxicant, nor did it adversely affect reproductive parameters. No evidence of qualitative or quantitative susceptibility was observed in developmental studies in rats and rabbits or in a multi-generation study in rats.

In an acute neurotoxicity study, transient decreased motor activity was seen only on the day of treatment, but no other findings demonstrating neurotoxicity were observed. In addition, no neurotoxicity was observed in the subchronic neurotoxicity study in the presence of other systemic adverse effects. Fluopyram did not produce treatment-related effects on the immune system.

Fluopyram has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Fluopyram is not a skin or eye irritant or sensitizer under the conditions of the murine lymph node assay.

Specific information on the studies received and the nature of the adverse effects caused by fluopyram 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 entitled ''Fluopyram: Human Health Risk Assessment for Proposed New Use as a Soil/In-Furrow Treatment for Cotton and Peanut, and as a Seed Treatment to Cotton and Soybean, Plus a Proposal for Amended Inadvertent Tolerances for the Crop Group 15 Cereal Grains and Crop Group 16 Forage, Fodder, and Straw of Cereal Grains'' in docket ID number EPA–HQ–OPP–2013–0662.

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.*

The details for selecting toxicity endpoints and points of departure for various exposure scenarios can be found at *http://www.regulations.gov* in the document entitled ''Fluopyram: Human Health Risk Assessment for Proposed New Use as a Soil/In-Furrow Treatment for Cotton and Peanut, and as a Seed Treatment to Cotton and Soybean, Plus a Proposal for Amended Inadvertent Tolerances for the Crop Group 15 Cereal Grains and Crop Group 16 Forage, Fodder, and Straw of Cereal Grains'' in docket ID number EPA–HQ–OPP–2013–0662.

A summary of the toxicological endpoints for fluopyram used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOPYRAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	An endpoint attributable to a single dose exposure has not been identified for this subpopulation.		
Acute dietary (General population including infants and children).	NOAEL = 50 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.50 mg/kg/day. aPAD = 0.50 mg/kg/day	Acute Neurotoxicity Study in Rats. LOAEL = 100 mg/kg/day based on decreased motor and locomotor activity in females. The LOAEL in males was 125 mg/kg/day.
Chronic dietary (All populations)	NOAEL = 1.2 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.012 mg/kg/day. cPAD = 0.012 mg/kg/day	Combined Chronic/Carcinogenicity in Rats. LOAEL = 6.0 mg/kg/day based on follicular cell hypertrophy in the thyroid, and increased liver weight with gross pathological and histopathological findings.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUOPYRAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhalation).	Classification: Not likely to be carcinogenic to humans at doses that do not induce cellular proliferation in the liver or thyroid glands.		

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).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluopyram, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopyram tolerances in 40 CFR 180.661. EPA assessed dietary exposures from fluopyram 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 fluopyram. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA included tolerance residue levels, the assumption of 100 percent crop treated (PCT), and processing factors (empirical and default).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/ WWEIA. As to residue levels in food, EPA included average field-trial residue levels, the assumption of 100 PCT, and processing factors (empirical and default).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopyram does not pose a cancer risk to humans at doses that do not induce cellular proliferation in the liver or thyroid glands. The chronic RfD is derived using the NOAEL of 1.2 mg/kg/day as the ''point of departure'' which is below the dose of 11 mg/kg/day that caused cell proliferation in the liver (*i.e.,* a key event in tumor formation) and the subsequent liver tumors at a higher dose (89 mg/kg/day). Therefore, the Agency believes the chronic assessment will be protective of any cancer risk; therefore, a separate dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluopyram in drinking water. These simulation models take into account data on the physical, chemical, and fate/ transport characteristics of fluopyram. 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 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of fluopyram for acute exposures are estimated to be 19.4 parts per billion (ppb) for surface water and 87.5 ppb for ground water. The chronic exposures for non-cancer assessments are estimated to be 4.9 ppb for surface water and 76.8 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 87.5 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 76.8 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). Fluopyram is not registered for any specific use patterns that would result in residential exposure.

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The available developmental toxicity studies in rats and rabbits and the multi-generation reproduction in rats

demonstrate no evidence of increased susceptibility in the developing or young animals, which were exposed during prenatal or postnatal periods. Decreased fetal body weight was observed at levels equal to or greater than the maternal LOAEL in both rat and rabbit developmental studies. Likewise, body-weight effects were seen in offspring at levels equal to the parental LOAEL in the rat 2-generation reproductive toxicity study.

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

i. The toxicity database for fluopyram is complete.

ii. The fluopyram toxicology database did not demonstrate evidence of neurotoxicity. Although transient decreases in motor and locomotor activities in the acute neurotoxicity study on the day of treatment and limited use of hind-limbs and reduced motor activity in the rat chronic/carcinogenicity study were seen, there were no other associated neurobehavioral or histopathology changes found in other studies in the fluopyram toxicity database. The effects seen in the chronic/carcinogenicity study were in the presence of increased mortality and morbidity such as general pallor and appearance. Therefore, the reduced motor activity and limited use of hind-limbs seen in these two studies were judged to be the consequence of the systemic effects and not direct neurotoxicity. Therefore, there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that fluopyram 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.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary exposure assessment was performed using tolerance level residues or average field-trial residues for all crops. Both acute and chronic assessments assumed 100 PCT and incorporated empirical or default processing factors. The dietary exposure assessment also assumed that all drinking water will contain fluopyram at the highest EDWC levels modeled by the Agency for ground or surface water. Residential exposures are not expected. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopyram in drinking water. These assessments will not underestimate the exposure and risks posed by fluopyram.

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 fluopyram will occupy 4.4% 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 fluopyram from food and water will utilize 38% of the cPAD for all infants, the population group receiving the greatest exposure. There are no residential uses for fluopyram. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopyram 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). Because there are no residential uses, short-term residential exposures are not likely to occur, and therefore fluopyram is not expected to pose a short-term aggregate risk.

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 there are no residential uses, intermediate-term residential exposures are not likely to occur, and therefore fluopyram is not expected to pose an intermediate-term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the data summarized in Unit III.A. and the lack of a chronic risk, fluopyram 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 fluopyram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The German multi-residue method DFG Method S 19, a gas chromatography with mass selective detection (GC/MSD) method, is adequate for the enforcement of tolerances for fluopyram residues in or on crop commodities, and a high performance liquid chromatography method with tandem mass spectrometry detection (HPLC/MS/MS), Method 01079, is adequate for the enforcement of tolerances for residues of fluopyram and its metabolite, AE C656948-benzamide, in livestock commodities. The validated limit of quantitation (LOQ) is 0.01 ppm for each analyte in each matrix. The enforcement methods for plant commodities (DFG Method S19) and livestock commodities (Method 01079) are deemed adequate as enforcement methods. Adequate HPLC/MS/MS methods were used for data collection for crop and livestock commodities. Thus, adequate enforcement methodologies (DFG Method S 19 and Method 01079) are available to enforce the tolerance expression.

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. As required by FFDCA section 408(b)(4), EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex) in its tolerance decisions. 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 MRL for peanut is 0.03 mg/kg, which is lower than the U.S. tolerance as amended for peanuts at 0.09 ppm. The U.S. peanut tolerance cannot be harmonized at 0.03 because following the approved label directions could result in residues above 0.03 ppm.

There are Codex MRLs for the livestock commodities that are higher than the U.S. tolerances for livestock commodities. The lowering of the tolerances for the cereal grains (group 15), and cereal grains forages, stovers, and straws (group 16), all as rotational crops, resulted in considerably less fluopyram in the livestock diets than under the previous tolerances. As a result, the tolerances for the livestock commodities were lowered. Calculated values were adjusted slightly to harmonize with Canada for all livestock commodity tolerances/MRLs but could not be harmonized with Codex MRLs, which are generally higher (5X–60X), because they are based on a different residue definition, do not reflect the North American Free Trade Agreement (NAFTA) plant commodity use patterns, and do not consider the Maximum Reasonably Based Diet.

C. Response to Comments

Two comments were received in response to the notice of filing of Bayer CropScience's application. Both commenters objected to the increase of chemical residues generally and one commenter expressed additional concerns about the carcinogenic effects of chemicals in general on humans. The Agency understands the commenters' 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 fluopyram, which included an assessment on the carcinogenic potential of fluopyram. Based on its assessment of the available data, the Agency has concluded that fluopyram 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 fluopyram.

D. Revisions to Petitioned-For Tolerances

EPA is establishing tolerances for cotton gin byproducts and for cereal grain forage group 16 that differ from the petitioned-for tolerances. The petitioned-for tolerances differ from the tolerances for cotton gin byproducts and for cereal grain forage group 16. The petition requested a tolerance of 0.80 ppm for cotton gin byproducts, but based on residue data provided and using the Organization for Economic Cooperation and Development (OECD) statistical calculation, EPA is establishing a tolerance level of 0.70 ppm. The petition also requested two different tolerances for the cereal grain forage, fodder, stover, and straw group 16: 1.5 ppm for forage and 2.0 ppm for hay, fodder, and straw. Only one tolerance is possible for the group, so the Agency is establishing the tolerance at 2.0 ppm to cover residues within that crop group.

EPA is establishing tolerances for fat, meat, and meat byproducts of cattle, hog, and poultry; egg; and milk lower than the petition requested based on a recalculation of the livestock dietary burdens and adjusted upwards to harmonize with Canada. The Agency is revising the commodity terms to ''cattle, fat''; ''cattle, meat''; and ''cattle, meat byproducts'' to be consistent with the food commodity vocabulary used for tolerances.

E. Trade Considerations

A few of the tolerance actions result in reductions of existing tolerance levels; therefore, EPA is delaying the effective date of the following tolerance actions for 6 months to allow a reasonable interval for producers in exporting member countries of the World Trade Organization's Sanitary and Phytosanitary Measures Agreement to adapt to the requirements of these modified tolerances. The tolerance actions subject to the 6-month delay are effective June 17, 2015 are as follows: Modifying tolerances in § 180.661(a)(2) for cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.40 ppm; egg at 0.06 ppm; hog, fat at 0.02 ppm; hog, meat at 0.02 ppm; hog, meat byproducts at 0.03 ppm; milk at 0.06 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; and poultry, meat byproducts at 0.10 ppm; modifying tolerances in § 180.661(d) for grain, cereal, group 15, except rice at 1.5 ppm to grain, cereal, except rice, group 15 at 0.03 ppm; establishing tolerances in § 180.661(d) for grain, cereal, forage, fodder and straw, group 16 at 2.0 ppm; and removing tolerances from § 180.661(d) for grain, cereal, forage, fodder and straw, group 16, except rice; forage at 4.0 ppm; grain, cereal, forage, fodder and straw, group 16, except rice; hay, straw and stover at 7.0 ppm; and soybean, seed at 0.10 ppm.

V. Conclusion

Therefore, tolerances are established for residues of fluopyram, *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide, including its metabolites and degradates in or on the following commodities: Cattle, fat at 0.05 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.40 ppm; cotton, gin byproducts at 0.70 ppm; cotton, undelinted seed at 0.01 ppm; egg at 0.06 ppm; grain, cereal, except rice, group 15 at 0.03 ppm; grain, cereal, forage, fodder and straw, group 16 at 2.0 ppm; hog, fat at 0.02 ppm; hog, meat at 0.02 ppm; hog, meat byproducts at 0.03 ppm; milk at 0.06 ppm; peanuts at 0.09 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.10; and soybean, seed at 0.04 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 9, 2014.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.661 (effective December 17, 2014):

■ a. Add alphabetically ''Cotton, gin byproducts''; ''Cotton, undelinted seed''; and ''Soybean, seed'' to the table in paragraph (a)(1).

■ b. Revise the entry for ''Peanut'' in the table in paragraph (a)(1).

■ c. Remove the entries ''Cotton, gin byproducts'' and ''Cotton, undelinted seed,'' in the table in paragraph (d).

The additions and revision read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Cotton, gin byproducts	0.70
Cotton, undelinted seed	0.01
* * * * *	
Peanut	0.09
* * * * *	
Soybean, seed	0.04
* * * * *	

* * * * *

■ 3. In § 180.661 (effective June 17, 2015):

■ a. Revise in the table in paragraph (a)(2) the following entries listed in the table below.

■ b. Add alphabetically ''Grain, cereal, except rice, group 15'' and ''Grain, cereal, forage, fodder and straw, group 16'' to the table in paragraph (d).

■ c. Remove the entries ''Grain, cereal, forage, fodder and straw, group 16, except rice; forage''; ''Grain, cereal, forage, fodder and straw, group 16, except rice; hay, straw and stover''; and ''Grain, cereal, group 15, except rice'' in the table in paragraph (d).

The additions and revisions read as follows:

§ 180.661 Fluopyram; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.40
Egg	0.06
* * * * *	
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.03
* * * * *	
Milk	0.06
Poultry, fat	0.03
Poultry, meat	0.03
Poultry, meat byproducts	0.10
* * * * *	

* * * * *

(d) * * *

Commodity	Parts per million
* * * * *	
Grain, cereal, except rice, group 15	0.03
Grain, cereal, forage, fodder and straw, group 16	2.0
* * * * *	

[FR Doc. 2014–29480 Filed 12–16–14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0352; FRL–9919–35]

Natamycin; Amendment to an Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide natamycin in or on pineapples. DSM Food Specialties B.V. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of natamycin in or on pineapple.

DATES: This regulation is effective December 17, 2014. Objections and requests for hearings must be received on or before February 17, 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–2014–0352, 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: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington,

DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2014–0352 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 17, 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–2014–0352, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of August 1, 2014 (79 FR 44729) (FRL–9911–67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F8233) by DSM Food Specialties B.V. (the Petitioner), Alexander Fleminglaan 1, 2613 AX Delft, The Netherlands. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of natamycin for post-harvest indoor use on pineapples. That document referenced a summary of the petition prepared by the Petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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. . . . '' Additionally, FFDCA section 408(b)(2)(D) requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information 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.

A. Overview of Natamycin

Natamycin is a naturally occurring compound derived from the common soil microorganisms *Streptomyces natalensis, Streptomyces lydicus,* and *Streptomyces chattanoogensis.* Natamycin was originally discovered in *Streptomyces natalensis* in South Africa in the early 1950s, and was subsequently discovered to also occur naturally in North America in *Streptomyces lydicus* and *Streptomyces chattanoogensis.* It is commercially produced by a submerged oxygen-based fermentation of *Streptomyces natalensis, Streptomyces lydicus,* or *Streptomyces chattanoogensis.* Natamycin has been used as a food preservative worldwide for over 40 years and is approved as a food additive/preservative by the European Union, the World Health Organization, and individual countries including New Zealand and Australia for use as a fungistat to suppress mold on cheese, meats, and sausage. In the United States, natamycin is approved by the Food and

Drug Administration (FDA) as a direct food additive/preservative for the inhibition of mold and yeast on the surface of cheeses (21CFR 172.155) and as an additive to the feed and drinking water of broiler chickens to retard the growth of specific molds (21CFR 573.685). Natamycin is also FDA approved for use as a treatment to suppress fungal eye infections such as blepharitis, conjunctivitis, and keratitis.

As a biochemical pesticide active ingredient, natamycin is already approved for use as a fungistat to prevent and control the germination of mold and yeast spores in the growth media of mushrooms produced in enclosed mushroom production facilities (77 FR 29543). Additional potential uses of natamycin include controlling fungal growth post-harvest on pineapples treated indoors. Natamycin has a non-toxic mode of action, has no effects on fungal mycelia, and development of antibiotic resistance to natamycin has not been reported during its entire history of use. See the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin'' (November 7, 2014), available in the docket for this action.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to amend the existing tolerance exemption by adding use as a fungicide post-harvest, indoors, on pineapples have been fulfilled. No toxic endpoints were established and no significant toxicological effects were observed in any of the acute toxicity studies. In addition, studies submitted indicate that natamycin is not genotoxic, has no subchronic toxic effects, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation routes of exposure. For a summary of the data upon which EPA relied, and its human health risk assessment based on that data, please refer to the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin'' (November 7, 2014). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

The proposed use patterns may results in dietary exposure to natamycin, however, exposure is expected to be insignificant (see document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin'' (November 7, 2014), available in the docket for this action. No significant exposure via drinking water is expected; natamycin is applied indoors only. Some dietary exposure to natamycin might occur through other nonpesticidal sources as a result of its use as a food additive/preservative. Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of natamycin as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin'' (November 7, 2014), available in the docket for this action.

B. Other Non-Occupational Exposure

Other non-occupational exposure (other than dietary) from pesticidal use is not expected because natamycin is not approved for residential uses. The active ingredient is applied directly to commodities and degrades rapidly. There may be some exposure to natamycin as a result of its use as treatment of infections, but minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of natamycin as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin'' (November 7, 2014), available in the docket for this action.

V. 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 natamycin to share a common mechanism of toxicity with any other substances, and natamycin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that natamycin 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.*

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) 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 that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on natamycin and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies, as fully explained in the document entitled, ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin'' (November 7, 2014), available in the docket for this action. Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants, children, or adults when natamycin is applied to mushrooms in

enclosed mushroom production facilities and on pineapples when used in accordance with label directions and good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Further, residues are not expected on any other crops because natamycin will only be applied indoors to these particular crops.

VIII. Conclusion

Based on its assessment of natamycin, 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 natamycin. Therefore, an amendment to the exemption of a tolerance is established for residues of natamycin in or on pineapple.

The Agency is issuing the exemption for residues on pineapple instead of limiting this exemption to post-harvest indoor applications to pineapple because the restrictions are not relevant to the FFDCA safety finding for natamycin. Those limitations are related to the use of the pesticide and regulated under FIFRA.

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 1, 2014.

Robert McNally,

Director, Biopesticides and Pollution Prevention 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. Revise § 180.1315 to read as follows:

§ 180.1315 Natamycin; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of natamycin in or on mushrooms when applied as a fungistat to prevent the germination of fungal spores on mushrooms produced in enclosed mushroom production facilities, and in or on pineapples when applied as a fungistat in accordance with label directions and good agricultural practices.

[FR Doc. 2014–29306 Filed 12–16–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket Nos. 130402317–3966–02 and 140429387–4971–02]

RIN 0648–XD659

Atlantic Highly Migratory Species; Commercial Porbeagle Shark Fishery

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

ACTION: Temporary rule; closure and addendum to the fishing season notification.

SUMMARY: NMFS is closing fishing for the commercial porbeagle shark quota until further notice. This action is necessary because, as of December 10, 2014, the commercial landings of porbeagle sharks during the 2014 fishing season exceeded the available 2014 adjusted commercial quota and to an extent that makes 2015 commercial quota unavailable.

DATES: Fishing for the commercial porbeagle shark quota is closed effective 11:30 p.m. local time, December 17,

2014, until and if NMFS announces via a subsequent document in the **Federal Register** that additional quota is available and the season is reopened. The provisions in this document supercede the January 1, 2015, commercial season opening date and commercial quota established for porbeagle sharks in a December 2, 2014 final rule (79 FR 71331). Fishing for the commercial porbeagle shark quota will not open on January 1, 2015; it will remain closed until subsequent notice is provided.

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)(1), when NMFS calculates that the landings for a species or management group that is not linked to another species or management group have reached or are projected to reach 80 percent of the available quota, NMFS will file for publication with the Office of the Federal Register a notice of closure for the species or management group that will be effective no fewer than 5 days from date of filing. From the effective date and time of the closure until NMFS announces, via a document in the **Federal Register**, that additional quota is available and the season is reopened, the fishery for that species or management group is closed, even across fishing years.

On November 26, 2013 (78 FR 70500), NMFS announced that the commercial porbeagle shark quota for 2014 was 1.2 metric tons (mt) dressed weight (dw) (2,820 lb dw). Dealer reports recently received through December 10, 2014, indicate that 2.5 mt dw (5,586 lb dw), or 198 percent, of the available 2014 commercial porbeagle shark quota has been landed. Dealer reports received and reviewed to date indicate that 9 percent of the quota was landed from the opening of the fishery on January 1, 2014, through May 13, 2014; 16 percent of the quota was landed by September 16, 2014; 37 percent was landed by October 15, 2014; 55 percent was landed by November 14, 2014; and 198 percent of the quota was landed by December 10, 2014. Accordingly, because the available 2014 commercial quota has been exceeded to an extent, as described below, that makes 2015 commercial quota unavailable, NMFS is closing fishing for the commercial porbeagle shark quota as of 11:30 p.m. local time, December 17, 2014, until further notice. This closure does not affect other shark species or management groups.

NMFS previously established a January 1, 2015 season opening date for the commercial porbeagle shark quota in a December 2, 2014 final rule (79 FR 71331). This document supercedes that provision in the December 2 final rule, and fishing for the commercial porbeagle shark quota will remain closed until further notice.

Also in that final rule, NMFS announced that the available 2015 commercial porbeagle shark quota was 1.7 mt dw (3,748 lb dw). As of December 10, 2014, the 2014 landings exceeded the 2014 commercial quota by 1.3 mt dw (5,586 − 2,820 lb dw = 2,766 lb dw). Accounting for this overharvest provides for a 2015 commercial quota of 0.4 mt dw (3,748 − 2,766 lb dw = 982 lb dw). It would be difficult to monitor such a small amount of quota and to timely assess when landings are projected to reach 80 percent of it in a way that allows NMFS to close fishing for the quota before overharvests would occur (*i.e.,* when landings reach 0.3 mt dw or 786 lb dw; § 635.28(b)(1)). Additionally, it is possible that additional porbeagle landings could be reported in 2014 before this closure becomes effective, making even less quota available for 2015. Thus, quota effectively is not available for the 2015 fishing season. Given the effect of the updated landings data on the availability of quota for 2015 and the regulatory closure provision that fishing for the commercial porbeagle shark quota remains closed, even across fishing years, until NMFS announces by **Federal Register** document that additional quota is available and the season is reopened (§ 635.28(b)(1)), fishing for the commercial porbeagle shark quota will not re-open on January 1, 2015; it will remain closed unless NMFS issues a subsequent document. Table 1 from the December 2, 2014 final rule is amended accordingly to reflect updated landings and actions (closure of fishery and change in available quota) associated with this document.

TABLE 1—2015 ANNUAL QUOTAS AND OPENING DATES FOR THE ATLANTIC SHARK FISHERIES

[All quotas and landings are dressed weight (dw), in metric tons (mt), unless specified otherwise]

Region	Management group	2014 Annual quota (A)	Preliminary 2014 landings [1] (B)	Adjustments (C)	2015 Base annual quota (D)	2015 Final annual quota (D + C)	Season opening dates
Gulf of Mexico	Blacktip Sharks	274.3 mt dw (604,626 lb dw).	202.3 mt dw (446,024 lb dw).	72.0 mt dw (158,602 lb dw) [2].	256.6 mt dw (565,700 lb dw).	328.6 mt dw (724,302 lb dw).	January 1, 2015.
	Aggregated Large Coastal Sharks.	151.2 mt dw (333,828 lb dw).	153.7 mt dw (338,923 lb dw).	−1.0 mt dw (2,337 lb dw) [3].	157.5 mt dw (347,317 lb dw).	156.5 mt dw (344,980 lb dw).	
	Hammerhead Sharks.	25.3 mt dw (55,722 lb dw).	14.4 mt dw (31,733 lb dw).	.....	25.3 mt dw (55,722 lb dw).	25.3 mt dw (55,722 lb dw).	
	Non-Blacknose Small Coastal Sharks.	68.3 mt dw (150,476 lb dw).	66.8 mt dw (147,366 lb dw).	.....	45.5 mt dw (100,317 lb dw).	45.5mt dw (100,317 lb dw).	
	Blacknose Sharks	1.8 mt dw (4,076 lb dw).	1.4 mt dw (3,149 lb dw).	−0.2 mt dw (−437 lb dw) [4].	2.0 mt dw (4,513 lb dw).	1.8 mt dw (4,076 lb dw).	
Atlantic	Aggregated Large Coastal Sharks.	168.9 mt dw (372,552 lb dw).	101.6 mt dw (224,098 lb dw).	.....	168.9 mt dw (372,552 lb dw).	168.9 mt dw (372,552 lb dw).	July 1, 2015.
	Hammerhead Sharks.	27.1 mt dw (59,736 lb dw).	6.0 mt dw (13,223 lb dw).	.....	27.1 mt dw (59,736 lb dw).	27.1 mt dw (59,736 lb dw).	

TABLE 1—2015 ANNUAL QUOTAS AND OPENING DATES FOR THE ATLANTIC SHARK FISHERIES—Continued

[All quotas and landings are dressed weight (dw), in metric tons (mt), unless specified otherwise]

Region	Management group	2014 Annual quota (A)	Preliminary 2014 landings [1] (B)	Adjustments (C)	2015 Base annual quota (D)	2015 Final annual quota (D + C)	Season opening dates
No regional quotas	Non-Blacknose Small Coastal Sharks.	264.1 mt dw (582,333 lb dw).	103.1 mt dw (227,202 lb dw).	.....	176.1 mt dw (388,222 lb dw).	176.1 mt dw (388,222 lb dw).	January 1, 2015.
	Blacknose Sharks	17.5 mt dw (38,638 lb dw).	17.4 mt dw (38,437 lb dw).	−0.5 mt dw (−1,111 lb dw) [4].	18.0 mt dw (39,749 lb dw).	17.5 mt dw (38,638 lb dw).	
	Non-Sandbar LCS Research.	50.0 mt dw (110,230 lb dw).	14.3 mt dw (31,543 lb dw).	.....	50.0 mt dw (110,230 lb dw).	50.0 mt dw (110,230 lb dw).	January 1, 2015.
	Sandbar Shark Research.	116.6 mt dw (257,056 lb dw).	37.5 mt dw (82,737 lb dw).	.....	116.6 mt dw (257,056 lb dw).	116.6 mt dw (257,056 lb dw).	
	Blue Sharks	273.0 mt dw (601,856 lb dw).	7.8 mt dw (17,157 lb dw).	.....	273.0 mt dw (601,856 lb dw).	273.0 mt dw (601,856 lb dw).	
	Porbeagle Sharks	1.2 mt dw (2,820 lb dw).	2.5 mt dw (5,586 lb dw).	−1.3 mt dw (−2,766 lb dw).	1.7 mt dw (3,748 lb dw).	0.4 mt dw (982 lb dw).	Closed [5]
	Pelagic Sharks Other Than Porbeagle or Blue.	488 mt dw (1,075,856 lb dw).	126.7 mt dw (279,276 lb dw).	.....	488.0 mt dw (1,075,856 lb dw).	488.0 mt dw (1,075,856 lb dw).	January 1, 2015.

[1] All landings except for the porbeagle shark landings are from January 1, 2014, through October 15, 2014, and are subject to change. Porbeagle shark landings are from January 1, 2014, through December 10, 2014.

[2] This adjustment accounts for underharvest in 2014. Therefore, the Gulf of Mexico blacktip shark adjusted quota will be 328.6 mt dw for the 2015 fishing season.

[3] This adjustment accounts for overharvests from 2013 and 2014. In the final rule establishing the 2014 quotas (78 FR 70500; November 26, 2013), the 2013 Gulf of Mexico aggregated LCS quota was overharvested by 6.2 mt dw (13,489 lb dw). After the final rule establishing the 2014 quotas published, late dealer reports indicated the quota was overharvested by an additional 0.1 mt dw (408 lb dw), for a total overharvest of 6.3 mt dw (13,897 lb dw). Recently, NMFS determined that the 2014 final rule overestimated the overharvest from 2013 by 1.3 mt dw (2,758 lb dw). In 2014, the Gulf of Mexico aggregated LCS quota was overharvested by 2.3 mt dw (5,095 lb dw). Therefore, this final rule reduces the Gulf of Mexico aggregated LCS quota by 1.0 mt dw (2.3 mt dw overharvest in 2014—1.3 mt dw overestimated from 2013). NMFS will adjust the 2015 base annual quota based on the updated overharvest estimates from 2013 and 2014.

[4] This adjustment accounts for overharvest in 2012. After the final rule establishing the 2012 quotas published, late dealer reports indicated the blacknose shark quota was overharvested by 3.5 mt dw (7,742 lb dw). In the final rule establishing the 2014 quotas, NMFS implemented a 5-year adjustment of the overharvest amount by the percentage of landings in 2012. Thus, NMFS will reduce the Gulf of Mexico blacknose shark quota by 0.2 mt dw (437 lb dw) and the Atlantic blacknose shark quota by 0.5 mt dw (1,111 lb dw) each year from 2014 through 2018. NMFS will reduce the 2015 base annual quota based on overharvest from 2012.

[5] This closure accounts for overharvest in 2014. After the final rule establishing the 2015 quotas published, dealer reports indicated that the porbeagle quota was overharvested by 1.3 mt dw (2,766 lb dw). Accounting for this large overharvest would result in a 2015 commercial quota of 0.4 mt dw (3,748 − 2,766 lb dw = 982 lb dw). It would be difficult to monitor such a small amount of quota and to timely assess when landings are projected to reach 80 percent of it in a way that allows NMFS to close the fishery before overharvests would occur (*i.e.,* when landings reach 0.3 mt dw or 786 lb dw; § 635.28(b)(1)).

During the closure, retention of porbeagle sharks is prohibited for persons fishing aboard vessels issued a commercial shark limited access permit (LAP) 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)). A shark dealer issued a permit pursuant to § 635.4 may not purchase or receive porbeagle sharks from a vessel issued an Atlantic shark LAP, except that a permitted shark dealer or processor may possess porbeagle sharks that were harvested, off-loaded, and sold, traded, or bartered, prior to the effective date of the closure and were held in storage. Under this closure, a shark dealer issued a permit pursuant to § 635.4 may, in accordance with state regulations, purchase or receive a porbeagle sharks 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.

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 further 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 further 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: December 12, 2014.

Emily H. Menashes,

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

[FR Doc. 2014–29552 Filed 12–12–14; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 140904753–4999–01]

RIN 0648–BE34

Magnuson-Stevens Act Provisions; Fisheries off West Coast States; Regulatory Amendment to Pacific Coast Groundfish Fisheries Trawl Rationalization Program for the Start of 2015

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

ACTION: Final rule.

SUMMARY: This action revises regulations for the Pacific coast

groundfish fishery with an implementation date of January 1, 2015. Final implementation of the 2015–2016 biennial harvest specifications and management measures will be delayed beyond January 1, 2015. NMFS has identified two issues that must be addressed prior to January 1, 2015, to prevent interruption of ongoing fisheries and to allow harvest of the total allowable and available groundfish. This action addresses those issues by revising groundfish regulations in two ways. First, this action reinstates a mechanism whereby NMFS can issue interim groundfish allocations at the beginning of the year in years when annual groundfish harvest specifications are not yet finalized, as is the case for January 1, 2015. Second, this action amends regulations to allow NMFS to issue that portion of the allowable catch currently allocated to an Adaptive Management Program (AMP) to quota shareholders until final criteria and a process for distribution of the AMP quota shares is developed and implemented.

DATES: Effective December 17, 2014.

ADDRESSES: Electronic copies of the Regulatory Impact Review (RIR) and Regulatory Flexibility certification analysis, categorical exclusion memorandum, and Environmental Assessment (EA) may be obtained from the National Marine Fisheries Service (NMFS) West Coast Regional office in Seattle, at 7600 Sand Point Way Northeast, Seattle, Washington 98115, phone: 206–526–6150.

FOR FURTHER INFORMATION CONTACT: Miako Ushio, phone: 206–526–4644; or email: *Miako.Ushio@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

This rule is accessible via the Internet at the Office of the Federal Register Web site at *https://www.federalregister.gov.* Background information and documents are available at the NMFS West Coast Region Web site at *http://www.westcoast.fisheries.noaa.gov/fisheries/groundfish/index.html* and at the Council's Web site at *http://www.pcouncil.org.*

Background

Biennial specifications for groundfish harvest will not be available by January 1, 2015. This final rule resolves two issues that must be addressed prior to January 1, 2015, to prevent interruption of ongoing fisheries and to allow harvest of the total allowable and available groundfish. First, this action reinstates provisions allowing NMFS to issue Pacific whiting and non-whiting groundfish species quota pounds (QP) to current quota shareholders in the Shorebased Individual Fishing Quota Program based on conservative estimates in years, such as 2015, when harvest specifications of those species are not known by January 1. Second, the 10 percent of non-whiting quota share (QS) reserved for an AMP, that has not yet been established, will continue to be 'passed through' to the fishery. This 10 percent will be issued to current QS holders in proportion to their non-whiting QS until implementation of appropriate AMP regulations. NMFS is extending the pro rata pass-through so that the fish authorized for harvest through the biennial specifications process will continue to be available to benefit the fishing industry, dependent communities, and consumers.

This final rule implements the same regulations that were described in detail in the proposed rule that published on October 10, 2014 (79 FR 61272). See the preamble to the proposed rule for additional background information on the fishery and on the regulations implemented in this final rule.

Comments and Responses

The proposed rule for this action published in the **Federal Register** on October 10, 2014 at 79 FR 61272, with a comment period that closed on November 10, 2014. NMFS received no comments.

Classification

The Administrator, West Coast Region, NMFS, had determined that the regulations allowing NMFS to issue interim allocations and to continue issuance of AMP pounds to quota shareholders in the Shorebased IFQ Program, which this final rule implements, are consistent with the national standards of the Magnuson-Stevens Act and other applicable laws.

NMFS finds good cause to waive part of the 30-day delay in effectiveness pursuant to 5 U.S.C. 553(d)(3), so that this final rule may become effective on December 17, 2014. Leaving the 2014 harvest specifications and management measures in place could cause harm to some stocks because those management measures are not based on the most current scientific information; it could also cause drastic management changes later in the year to prevent exceeding some lower 2015 harvest specifications once they are implemented. Further, it would be contrary to the public interest to delay implementation of the AMP pass-through, because making this regulatory change allows harvest to continue as intended by the Council, consistent with the best scientific information available. Delaying this rule could cause economic harm to fishery participants because inaccurate amounts of QP could be issued pending finalization of the 2015 harvest specifications. This rule does not impose any new requirements or burdens on fishery participants, so there is no need to allow additional time for participants to make gear changes or change their fishing practices. These reasons constitute good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness.

An Environmental Assessment (EA) was prepared for the pass-through of adaptive management quota pounds portion of this proposed action, and can be found on the NMFS' Groundfish Trawl Catch Share Web site at *www.westcoast.fisheries.noaa.gov/fisheries/groundfish_catch_shares.* In approving the regulations allowing NMFS to continue issuance of AMP pounds to quota shareholders in the Shorebased IFQ Program, NMFS issued a Finding of No Significant Impact (FONSI) identifying the selected alternatives. A copy of the FONSI is available from NMFS (see **ADDRESSES**).

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 the 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.

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

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Indian fisheries.

Dated: December 11, 2014.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 660 as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.* and 16 U.S.C. 773 *et seq.*

■ 2. In § 660.140, revise paragraphs (d)(1)(ii)(A) introductory text,

(d)(1)(ii)(A)(*1*) and (*2*), (d)(1)(ii)(B)(*1*) and (*2*), and paragraph (l)(2) to read as follows:

§ 660.140 Shorebased IFQ Program.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) *Non-whiting QP annual sub-allocations.* NMFS will issue QP for IFQ species other than Pacific whiting and Pacific halibut annually by multiplying the QS permit owner's QS for each such IFQ species by that year's shorebased trawl allocation for that IFQ species. Deposits to QS accounts for IFQ species other than Pacific whiting and Pacific halibut will be made on or about January 1 each year. Until the implementation of any regulatory changes developed pursuant to the first program review for the trawl rationalization program, the resulting AMP QP will be issued to all QS permit owners in proportion to their non-whiting QS.

(*1*) In years where the groundfish harvest specifications are known by January 1, deposits to QS accounts for IFQ species will be made on or about January 1.

(*2*) In years where the groundfish harvest specifications are not known by January 1, NMFS will issue QP in two parts. On or about January 1, NMFS will deposit QP based on the shorebased trawl allocation multiplied by the lower end of the range of potential harvest specifications for that year. After the final harvest specifications are established later in the year, NMFS will deposit additional QP to the QS account.

* * * * *

(B) * * *

(*1*) In years where the Pacific whiting harvest specification is known by January 1, deposits to QS accounts for Pacific whiting will be made on or about January 1.

(*2*) In years where the Pacific whiting harvest specification is not known by January 1, NMFS will issue Pacific whiting QP in two parts. On or about January 1, NMFS will deposit Pacific whiting QP based on the shorebased trawl allocation multiplied by the lower end of the range of potential harvest specifications for Pacific whiting for that year. After the final Pacific whiting harvest specifications are established later in the year, NMFS will deposit additional QP to QS accounts.

* * * * *

(l) * * *

(2) *AMP QP pass through.* The 10 percent of non-whiting QS will be reserved for the AMP, but the resulting AMP QP will be issued to all QS permit owners in proportion to their non-whiting QS until the implementation of any regulatory changes developed pursuant to the first program review for the trawl rationalization program.

[FR Doc. 2014–29555 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 79, No. 242
Wednesday, December 17, 2014

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. FSIS–2014–0040]

RIN 0583–AD57

Eligibility of Lithuania To Export Meat and Meat Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: USDA's Food Safety and Inspection Service (FSIS) is proposing to add the Republic of Lithuania (Lithuania) to the list of countries eligible to export meat and meat products to the United States. FSIS's review of Lithuania's laws, regulations, and inspection implementation show that its meat inspection system requirements are equivalent to the Federal Meat Inspection Act (FMIA) and its implementing regulations.

Under this proposal, meat from cattle, sheep, swine, and goats slaughtered in Lithuania, or parts or other products thereof, processed in certified Lithuanian establishments, would be eligible for export to the United States. All such products would be subject to reinspection at United States ports-of-entry by FSIS inspectors.

DATES: Comments must be received on or before February 17, 2015.

ADDRESSES: FSIS invites interested persons to submit comments on this rule. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the online instructions at that site for submitting comments.
- Mail, including CD–ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.
- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2014–0040. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend the Federal meat inspection regulations to add Lithuania to the list of countries eligible to export meat and meat products to the United States (9 CFR 327.2(b)). Lithuania is not currently listed as eligible to export such products to the United States.

Statutory Basis for Proposed Action

Under the FMIA and the regulations that implement it, meat and meat products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States (21 U.S.C. 620). The FMIA also requires that the livestock from which such imports are produced be slaughtered and handled in connection with slaughter in a manner that is consistent with the Humane Methods of Slaughter Act (7 U.S.C. 1901–1906). Section 327.2 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export meat and meat products to the United States.

Paragraph 327.2(a) of 9 CFR requires that a foreign country's meat inspection system provide standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem inspection, humane methods of slaughter and handling, and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering and preparation of product by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the FMIA and its implementing regulations (9 CFR 327.2(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification and residue standards; and (7) any other inspection requirements (9 CFR 327.2(a)(2)(i)).

A foreign country's inspection system must be evaluated by FSIS before eligibility to export meat and meat products to the United States can be granted. This evaluation consists of two processes: A document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program. FSIS requests that countries provide information about their inspection systems through its self-reporting tool (SRT).[1] Through the SRT, FSIS collects

[1] The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection

Continued

information on practices and procedures in six areas, known as equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. FSIS evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an onsite review is scheduled using a multidisciplinary team to evaluate all aspects of the country's inspection program. This comprehensive process is described more fully on the FSIS Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview*.

The FMIA and implementing regulations require that foreign countries be listed in the CFR as eligible to import meat and meat products into the United States. FSIS must engage in rulemaking to list a country as eligible. Countries found eligible to import meat or meat products into the United States are listed in the meat inspection regulations at 9 CFR 327.2(b). Once listed, the government of an eligible country must certify to FSIS that establishments that wish to export meat products to the United States are operating under requirements equivalent to those of the United States (9 CFR 327.2(a)(3)). Countries must renew certifications of establishments annually.

Section 20 of the FMIA (21 U.S.C. 620) prohibits importing into the United States adulterated or misbranded carcasses, parts of carcasses, meat, or meat products of amenable species, which are capable of use as human food. To verify that products imported into the United States are not adulterated or misbranded, FSIS reinspects and randomly samples those products at import, before they enter U.S. commerce.

Evaluation of the Lithuanian Meat Inspection System

In 2004, the government of Lithuania initially requested approval to export meat, poultry, and egg products to the United States. After several consultations and FSIS visits to Lithuania, the country amended its request to include only meat and meat products in January 2012. If approved, Lithuania stated its immediate intent to export canned, dried, or smoked meat products of beef and pork to the United States. However, if approved, Lithuania would not be precluded from exporting other meat products in the future provided the products meet all applicable requirements for those products established by the USDA's Animal and Plant Health Inspection Service (APHIS) as well as by FSIS.

FSIS conducted a document review of Lithuania's meat (slaughter and processing) inspection system through information provided through the SRT to determine whether that system is equivalent to the United States' meat inspection system. Based on that review, FSIS concluded that Lithuania's laws, regulations, control programs, and procedures were sufficient to achieve the level of public health protection required by FSIS.

Accordingly, FSIS proceeded with an initial on-site audit of Lithuania's meat inspection system from September 10 to 26, 2012, to verify whether Lithuania's State Food and Veterinary Service (SFVS), which is Lithuania's central competent authority in charge of food inspection, effectively implemented a meat inspection system equivalent to that of the United States. FSIS concluded that Lithuania's meat inspection system met each equivalence component except sanitation. FSIS found that Lithuania had modified its inspection requirements since the document review, and no longer required written standard operating procedures for sanitation (Sanitation SOPs) from establishments. Additionally, the sanitation programs at all of the establishments visited by the audit team lacked measures to prevent recurring deficiencies that could result in direct product contamination or adulteration.

The initial on-site audit revealed other issues of concern, but none that resulted in a failure to meet the other five equivalence components. SFVS took immediate corrective actions to address the audit team's findings and provided a corrective action plan, which included new regulations, procedures, implementation measures, and verification activities. FSIS reviewed the plan and concluded that it addressed all of the audit findings. The initial audit report contains a full discussion of the corrective actions proffered by SFVS: *http://www.fsis.usda.gov/wps/wcm/connect/600646a6-75fb-4d24-b82e-02361c06f3db/Lithuania-2012.pdf?MOD=AJPERES.*

FSIS conducted a second on-site audit from September 16 to 24, 2013, to verify that Lithuania had satisfactorily implemented all the laws, regulations, and instructions to the field that FSIS found to be equivalent during the document analysis and to verify that all outstanding issues identified during the previous audit had been resolved. FSIS concluded, based on this audit, that Lithuania had satisfactorily addressed all audit findings and had met the FSIS equivalence criteria for all six components. For example, during the audit, FSIS verified that Lithuania had reestablished a regulatory requirement that establishments develop and maintain written Sanitation SOPs as a condition for gaining certification to export meat products to the U.S. FSIS also verified that Lithuania's inspection system has established official procedures to verify that each establishment has an effective sanitation program that meets the regulatory requirements, including development and maintenance of Sanitation SOPs.

Similarly, FSIS previously found that the SFVS did not ensure that establishments' HACCP corrective actions included preventive measures, or that establishments were documenting their monitoring or verification activities. During the most recent audit, FSIS verified that inspection program personnel are now effectively performing verification activities designed to ensure that establishments are properly documenting their monitoring and verification activities and are documenting preventive measures in response to HACCP system deviations.

In summary, FSIS has completed the document review, on-site audit, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has determined that, as implemented, Lithuania's meat inspection system (slaughter and processing) is equivalent to the United States' meat inspection system. The full report on Lithuania's meat inspection system (slaughter and processing) can be found on the FSIS Web site at: *http://www.fsis.usda.gov/wps/wcm/connect/87776212-0dec-44c3-8ee4-155ad0a02b15/Lithuania_2013_FAR.pdf?MOD=AJPERES.*

Should this rule become final, the Government of Lithuania must certify to FSIS that those establishments that wish to export meat or meat products to the United States are operating in accordance with requirements equivalent to those of the United States. FSIS will verify that the establishments certified by Lithuania's government are

systems according to the six equivalence components and as required by 9 CFR 327.2(a)(2)(iii). FSIS asks foreign governments to submit documentation, such as their inspection system laws, regulations, and policy issuances, that supports their responses to the SRT questions.

meeting the United States' requirements through periodic, regularly scheduled audits of Lithuania's meat inspection system. Certified establishments may export to the United States any meat or meat products from cattle, sheep, swine, and goats (9 CFR 327.2(b)).

Although a foreign country may be listed in FSIS's regulations as eligible to export meat and meat products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of APHIS' regulations, which also regulate the export of meat products from foreign countries to the United States.

If this proposed rule is adopted, all meat and meat products exported to the United States from Lithuania will be subject to reinspection at U.S. ports-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

In addition, FSIS will conduct other types of reinspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis for the detection of drug and chemical residues, pathogens, species, and product composition. Products that pass reinspection will be stamped with the official USDA mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry, and within 45 days they must be returned to the country of origin, destroyed, or converted to animal food (subject to approval by the Food and Drug Administration), depending on the violation. The import reinspection activities can be found on the FSIS Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures/fsis-import-reinspection/CT_Index9.*

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a ''non-significant'' regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Expected Cost of the Proposed Rule

If this rule is finalized, Lithuania intends to start with exporting canned, dried, or smoked beef and pork products to the United States. As noted above, if this rule is finalized, Lithuania would not be precluded from exporting other meat products in the future if the products meet all applicable APHIS and FSIS requirements for those products. Lithuania, however, will not be limited to the export of canned, dried, or smoked beef and pork products only. Given the limited market in the United States for Lithuanian meat products and Lithuania's low projected export volume, there is likely to be little, if any, impact on the United States economy.

Lithuania is a small beef producer with limited beef export capacity. Its maximum beef export to the world was achieved in 2011, when it exported $130 million, or 25,000 metric tons (MT), worth of beef,[2] mainly to the European Union and Russia.

Based on analysis of Lithuania's exports to Russia,[3] FSIS estimates that Lithuania has an excess beef export capacity of $26 million ($130 million − $104 million = $26 million) in value, or 3,000 MT (25,000 MT − 22,000 MT = 3,000 MT) in volume, that could be exported to the United States.

Accordingly, allowing Lithuanian beef exports to enter the 13,050,000 MT[4] United States beef market is expected to have minimal effect (3,000 MT represents a 0.023% increase), leaving the total United States beef supply almost unchanged. Because importing beef from Lithuania is not expected to greatly alter the United States beef supply, it will not contribute to any price change in that market.

Lithuanian data from CY 2013[5] shows that this country has reached its maximum pork export capacity, meaning it will export little, if any, pork to the United States. Considering that the United States pork supply is 11,212,000 MT (CY 2013),[6] it is unlikely that imports from Lithuania will result in price changes in the United States pork market.

The above cost analysis is based on Lithuania's full export capacity. Currently, however, only six Lithuanian establishments intend to export product to the United States. Four are meat processors only, one is a slaughter facility, and one conducts both meat slaughter and processing. Of the four processing facilities, three process beef and pork, and one processes pork only. The slaughter-only facility and the facility that conducts both slaughter and processing both handle beef and pork. The combined export capacity of these six establishments is much less than Lithuania's total export capacity. With no price change expected in U.S. meat markets, adopting this proposed rule would lead to no negative effects on U.S. consumers.

Lithuanian companies that export product to the U.S. or U.S. companies that import products from Lithuania to the United States will incur standard costs such as export fees and freight and insurance costs. They will be willing to bear these costs, however, because of the anticipated financial benefits associated with marketing their products in the United States.

Expected Benefits of the Proposed Rule

Adoption of this proposed rule will increase trade between the United States and Lithuania. The volume of trade stimulated by the proposed rule is likely to be small and is expected to have little or no effect on U.S. meat supplies or meat prices. U.S. consumers, however, are expected to enjoy more choices when purchasing meat and meat products. Lithuanian establishments seek to export commercially sterile meat products, including canned meat products and ready-to-eat products like salamis and other dried and smoked meats to the United States. The proposed rule would, therefore, expand choices for U.S. consumers and promote economic competition.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

[2] This data is from Eurostat, the statistical office of the European Union, and is based on Lithuania's official statistics. It is also available at the Global Trade Atlas database at: *http://www.gtis.com/gta/secure/gateway.cfm.*

[3] Ibid.

[4] Source: Foreign Agricultural Service (FAS) Production, Supply and Distribution (PSD) data, available at: *https://apps.fas.usda.gov/psdonline/psdQuery.aspx.*

[5] This data is from Eurostat, based on Lithuania's official statistics. It is also available at the Global Trade Atlas database at: *http://www.gtis.com/gta/secure/gateway.cfm.*

[6] Source: FAS PSD data, available at: *https://apps.fas.usda.gov/psdonline/psdQuery.aspx.*

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export meat and meat products to the United States are required to provide information to FSIS certifying that their inspection systems provide standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Lithuania with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583–0153. The proposed rule contains no other paperwork requirements.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted, (2) no retroactive effect will be given to this rule, and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail

U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410.

Fax

(202) 690–7442.

Email

program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 327

Imported products.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 327 as follows:

PART 327—IMPORTED PRODUCTS

■ 1. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 327.2 [Amended]

■ 2. Section 327.2 is amended in paragraph (b) by adding ''Lithuania'' in alphabetical order to the list of countries.

Done at Washington, DC, on: December 12, 2014.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2014–29605 Filed 12–16–14; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF ENERGY

10 CFR Part 951

[Docket Number: DOE–HQ–2014–0021]

RIN 1990–AA39

Convention on Supplementary Compensation for Nuclear Damage Contingent Cost Allocation

AGENCY: Office of General Counsel, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Energy (DOE or the Department) proposes to issue regulations under section 934 of the Energy Independence and Security Act of 2007. These regulations will establish a retrospective risk pooling program by which nuclear suppliers are expected to provide funds in the same amount as what the United States government would be obligated to contribute to an international supplementary fund under the Convention on Supplementary Compensation for Nuclear Damage in the event of certain nuclear incidents not covered by the Price-Anderson Act. The risk pooling program will involve a premium to be assessed retrospectively (*i.e.,* a deferred payment made only if a nuclear incident occurs) based on a risk-informed assessment formula taking into account specified risk factors and exclusionary criteria to provide a fair and equitable proration of costs among U.S. nuclear suppliers benefited by the Convention on Supplementary Compensation for Nuclear Damage.

DATES: *Meeting:* DOE will hold an information session open to the public on January 7, 2015, from 10:00 a.m. to 12:00 noon in Washington, DC.

Comments: DOE will accept comments, data, and information

regarding this notice of proposed rulemaking (NOPR) before and after the public meeting(s), but no later than March 17, 2015.

ADDRESSES: The information session will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585–0121. To attend, please notify Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.* See section IV, ''Public Participation,'' for additional information and participant instructions. Additionally, DOE intends to conduct public workshop(s) on the proposed rulemaking. The date, time and place of such workshop(s) will be announced in subsequent **Federal Register** notice(s).

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 RIN 1990–AA39, by either of the following methods:

- *Email: Section934Rulemaking@Hq.Doe.gov.*
- *Mail:* Ms. Sophia Angelini, U.S. Department of Energy, Office of the General Counsel, Mailstop GC–72, Section 934 Rulemaking, 1000 Independence Avenue SW., Washington, DC 20585. Please submit one signed original and three copies of all comments submitted by mail.

Instructions: All submissions received must include the agency name, docket number (DOE–HQ–2014–0021), and the RIN for this rulemaking. Note that all comments received will be posted without change, including personal information.

Docket: For access to the docket to read background documents or comments received, go to the *Federal eRulemaking Portal* at *http://www.regulations.gov,* or the Web site specifically established for this proceeding at *http://www.energy.gov/gc/convention-supplementary-compensation-rulemaking.*

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to Sophia Angelini (see contact information above) and by email to *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Sophia Angelini, Attorney-Advisor, Office of the General Counsel for Civilian Nuclear Programs, GC–72, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; telephone (202) 586–0319.

SUPPLEMENTARY INFORMATION:

I. Authority and Background

On December 19, 2007, the President signed into law the Energy Independence and Security Act of 2007 (the Act) (Pub. L. 110–140). Section 934 of the Act, ''Convention on Supplementary Compensation Contingent Cost Allocation,'' addresses how the United States will meet its obligation under the Convention on Supplementary Compensation for Nuclear Damage (CSC or Convention), adopted in Vienna on September 12, 1997 at the International Atomic Energy Agency (IAEA) to pay into a supplementary compensation fund created by the Convention. The Convention provides the basis for a global nuclear liability regime where victims of nuclear incidents are provided prompt and meaningful compensation and suppliers in the nuclear energy industry are provided consistent rules for dealing with legal liability. The Convention provides an umbrella instrument that can accommodate both countries that belong to an existing nuclear liability treaty, such as the Paris Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960 (Paris Convention), or the Vienna Convention on Civil Liability for Nuclear Damage of 21 May 1963 (Vienna Convention), and countries that do not now belong to any nuclear liability treaty but accept the basic principles of nuclear liability law embodied in those treaties. At present, the Convention has been signed by 18 countries and ratified by 5 countries—Argentina, Morocco, Romania, United Arab Emirates, and the United States. With the recent approval of ratification of the Convention by the Japanese Diet, it is expected that Japan will deposit its instrument of ratification with the IAEA in the near future, and that the Convention will come into force and effect 90 days thereafter.

A major feature of the Convention is the creation of an ''international supplementary fund,'' which provides an additional (second) tier of compensation not otherwise available under a State's national law and to which each party to the Convention contributes. It is only this second tier of compensation that United States' nuclear suppliers would be required to fund.

The first tier of compensation is provided by the State where the nuclear incident occurred [1] (the installation state), and is set in the Convention at a minimum of 300 million Special Drawing Rights (SDRs [2]). If that amount is insufficient, a second tier of compensation—the international supplementary fund—is available, funded by contributions from the CSC member States. The amount of the second tier compensation is determined by a formula prescribed in the Convention in Article IV. A CSC member State's contribution is the lower of the amount determined under Article IV.1(a) or Art. IV.1(c). The contribution amount under Article IV.1(a)is based on a CSC member State's: (1) Nuclear generating capacity (thermal power shown at the date of the nuclear incident in a list of nuclear installations established under Article VIII); and (2) the United Nations (UN) assessment rate. The United States' UN assessment rate for 2014–2015 is 22%. In the alternative, Article IV.1(c) establishes a cap on the contribution amount owed by any one CSC member State (other than the installation state) per nuclear incident. The cap phases out as the collective installed nuclear capacity of countries covered by the Convention increases.

The United States could owe as little as approximately $70 million (plus a proportional amount of potential additional interest and costs awarded by a court as provide in Article III.4 of the Convention) when the Convention

[1] For nuclear incidents occurring in the United States, the Price-Anderson Act would provide the coverage required under the Convention for the first tier of compensation, to which United States' nuclear suppliers are not required to contribute.

[2] SDR is the unit of account defined by the International Monetary Fund (IMF) and used by the IMF for its own operations and transactions. In July, 2014, 1 SDR equaled about $1.54; therefore, 300 million SDRs would equal roughly $462 million dollars. Current information on the SDR conversion rates can be found at *http://www.imf.org/external/np/exr/facts/sdr.htm.*

comes into force initially.[3] Assuming for example the 30 countries that have nuclear operating capacity in 2014 joined the CSC,[4] the United States would owe approximately $150 million.[5]

Section 934 of the Act establishes a retrospective risk pooling program by which United States nuclear suppliers are expected to provide funds in the same amount as what the United States government would be obligated to contribute as a CSC party, with respect to nuclear incidents not covered by the Price-Anderson Act, to the international supplementary fund created by the Convention. Section 934 authorizes the Department to promulgate regulations to implement the retrospective risk pooling program. Section 934 also specifies risk factors to be considered by DOE in developing the risk-informed assessment formula, including criteria for excluding certain goods and services or nuclear suppliers from the formula. Section 934(e)(2)(C).

On July 27, 2010, the Department published in the **Federal Register** a Notice of Inquiry (NOI) (75 FR 43945) and request for comment from the public on its development of regulations to implement section 934. In the NOI, the Department provided the public with a comprehensive background and explanation of the Convention, the scope, purpose and requirements of section 934, and the Department's deliberations on how to structure a draft regulation to effectuate the purposes and direction provided by Congress to the Department in section 934. The NOI may be referred to for additional background information on the Convention and section 934.

The comment period on the NOI was extended twice (75 FR 51986, August 24, 2010 and 75 FR 64717, October 20, 2010) in response to requests from the public. The extended comment period provided the public with opportunity to review and provide detailed comments in response to the NOI. The Department received comments from eleven organizations representing various elements of the nuclear industry. All such comments were posted and are available for review at *http://www.energy.gov/gc/convention-supplementary-compensation-rulemaking.* In addition, summaries of meetings with individual commenters who provided further input are available at *http://www.energy.gov/gc/ex-parte-communications.* A summary of the major comments received and the Department's responses are provided herein under the section-by-section analysis of this proposed rule.

II. Summary of the Proposed Rule

A. Overview of the Proposed Rule

This proposed rule establishes a new part 951 in Title 10 of the Code of Federal Regulations (CFR), which sets forth the requirements for U.S. nuclear suppliers to report on their nuclear export transactions and, if called upon, contribute a risk premium payment to the retrospective risk pooling program. The Department proposes two alternative formulas to calculate the risk premium payment of a nuclear supplier.

Subpart A sets forth the purpose and scope of the regulation, as well as proposed definitions. The purpose and scope of the regulation follows the direction in section 934 that DOE establish a risk-informed assessment formula to be used in determining the risk premium payment due by a nuclear supplier in the event of a nuclear incident outside the United States that results in a request for funds under the Convention and is not a Price-Anderson incident. The definitions section includes definitions drawn directly from section 934 of the Act, as well as additional terms necessary to operation of the regulation.

Subpart B sets forth provisions for establishment of the retrospective risk pooling program. Two alternative regulatory approaches are proposed for calculating the risk-informed assessment formula: (1) A risk-informed assessment formula by nuclear goods and services; or (2) a risk-informed assessment formula by nuclear sector. Both alternatives establish a risk-informed assessment formula to determine a nuclear supplier's retrospective risk premium payment. In addition, both alternatives provide criteria for exclusion of small nuclear suppliers, and a cap on the amount any one nuclear supplier would owe under the program. The primary difference in the alternatives rests with the method of expressing risk—where risk refers to the likelihood a nuclear supplier's goods or services would contribute to, and the nuclear supplier would be potentially liable for claims for damage resulting from, a nuclear incident at a covered installation resulting in a call for funds under the Convention—for purposes of calculating the retrospective risk premium. The first alternative expresses risk in terms of the specific goods or services provided by a nuclear supplier; the second alternative expresses risk in terms of the nuclear sector to which a nuclear supplier's goods or services are supplied. Regulatory text for both alternatives is set forth at the end of the proposal.

Subpart C sets forth the timing and method for payments to be made to the United States in the event of a call for funds under the Convention. Nuclear suppliers may pay the full amount upon notification by the Department of a required risk premium payment, or prorate the full amount over a five-year period, including applicable interest on the unpaid balance. In addition, Subpart C establishes the penalty amount if a supplier does not make the required payment.

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[3] This amount is illustrative only and assumes the following: 6 Contracting Parties to the CSC (Argentina, Canada, Japan, Morocco, Romania and the United States); one SDR equals $1.54; the United States UN assessment rate is 22%; the United States installed capacity is 307,000 MW thermal; and the aggregate installed capacity of all Contracting Parties is 450,000 MW thermal. Under Article IV.1(a) the contribution amount would be $154,308,000, under Article IV.1(c) $68,607,000; accordingly, the amount owed by the United States would be the lower amount, $68,607,000.

The following provides additional information on how these amounts were calculated. The calculation under Article IV.1(a) is the sum of the amounts under 1(a)(i) and (ii): (i) $141,834,000 [307,000 MW (U.S. installed capacity) × 300 SDRs ($462 per SDR) = $141,834,000] plus (ii) $12,474,000 [ratio of the U.S. UN rate (22%) to the total UN rate of all Contracting Parties (36.62%) = 60%; amount under (i) for all Contracting Parties = 450,000 MW × 300 SDRs ($462 per SDR) = $207,900,000; 10% of that sum = $20,790,000; 60% of $20,790,000 = $12,474,000], which equals $154,308,000. The calculation under Article IV.1(c) is the product of (1) the U.S. UN rate of assessment plus 8 points, 30%, times (2) the total contributions of all Contracting Parties under subsection (b), $228,690,000 [$207,900,000 (450,000 MW x 300 SDRs ($462 per SDR)) + $20,790,000 (10% of 207,900,000) = $228,690,000], which equals $68,607,000.

[4] Information on the 30 countries with operable nuclear power capacity in 2014 can be found at the World Nuclear Association Web site, *http://www.world-nuclear.org/info/Facts-and-Figures/World-Nuclear-Power-Reactors-and-Uranium-Requirements/.*

[5] This amount is illustrative only and assumes the following: 30 Contracting Parties to the CSC; one SDR equal $1.54; the United States UN assessment rate is 22%; the United States installed capacity is 307,000 MW thermal; and the aggregate installed capacity of all Contracting Parties is 1,000,000 MW thermal. Under Article IV.1(a), the contribution amount would be $154,770,000; under Article IV.1(c) the amount would be $182,952,000; accordingly, the amount owed by the United States would be the lower amount, $154,770,000.

The following provides additional information on how these amounts were calculated. The calculation under Article IV.1(a) is the sum of the amounts under 1(a)(i) and (ii): (i) $141,834,000 [307,000 MW (U.S. installed capacity) × 300 SDRs ($462 per SDR) = $141,834,000] plus (ii) $12,474,000 [ratio of the U.S. UN rate (22%) to the total UN rate of all Contracting Parties (79.64%) = 28%; amount under (i) for all Contracting Parties = 1,000,000 MW x 300 SDRs ($462 per SDR) = $462,000,000; 10% of that sum = $46,200,000; 28% of $46,200,000 = $12,936,000], which equals $154,770,000. The calculation under Article IV.1(c) is the product of (1) the U.S. UN rate of assessment plus 14 points, 36%, times (2) the total contributions of all Contracting Parties under subsection (b), $508,200,000 [$462,000,000 (1,000,000 MW × 300 SDRs ($462 per SDR)) + $46,200,000 (10% of 462,000,000) = $508,200,000], which equals $182,952,000.

Subpart D sets forth the information collection requirements associated with the administration of the retrospective risk pooling program. Those requirements include an initial report six months after the effective date of the rule, in which respondents describe each reportable transaction that occurred prior to the date of the rule, and an annual report thereafter. The information to be provided by a nuclear supplier includes: (1) Description of the reportable transaction; (2) date of the transaction; (3) location of the nuclear installation(s) involved in the transaction; (4) volume or quantity of certain nuclear goods or services provided; and (5) value (in U.S. dollars) of the goods or services provided.

The appendices to the rule, applicable only under Alternative 1, set forth the list of specific primary and secondary nuclear items that form the basis for calculating the risk premium payment. The items are ranked as primary or secondary, and weighted as 2 or 1, respectively, in accordance with the likelihood the good or service would provide the basis for a claim for damage resulting from a nuclear incident giving rise to a call for funds under the Convention. Alternative 2 does not reference a list of goods and services; however, this alternative is based on a similar weighting system to differentiate risk among the goods and services provided by a nuclear supplier within each nuclear sector.

B. Section-by-Section Analysis and Discussion of Response to Comments Received on the Notice of Inquiry

Subpart A—General Provisions

Section 951.1 and 951.2—Purpose and Scope

The Department is proposing these regulations to implement a retrospective risk pooling program in accordance with section 934 of the Act. Section 934 calls for establishment of a retrospective risk pooling program in which United States nuclear suppliers are required to participate and cover their allocated share of the contingent costs resulting from a covered incident that is not a Price-Anderson incident. (A Price-Anderson incident is defined at subsection 934(b)(8) to mean a covered incident for which the Price-Anderson Act (section 170 of the Atomic Energy Act of 1954) would make funds available to compensate for public liability). The amount each nuclear supplier is required to contribute is determined by application of a risk-informed assessment formula developed by the Department. The program is retrospective, *i.e.,* payment by a nuclear supplier is deferred and not due unless and until the United States is called upon to contribute to the international supplementary fund. The deferred payment is, in essence, the nuclear supplier's premium for insurance against the potential liability for nuclear damage covered by the Convention. The regulations only cover the retrospective premium a nuclear supplier would be obligated to pay in the case of a nuclear incident outside the United States and not a Price-Anderson incident (a Price-Anderson incident may occur outside the United States if it arises from U.S.-owned nuclear material and involves activities conducted by or on behalf of DOE). The retrospective risk pooling program is not invoked where a nuclear incident occurs inside the United States.

All of the comments received by the Department on the NOI expressed support for the Convention and ratification of this international convention by the United States. The commenters supported the goal of adherence to a global nuclear liability regime to provide a predictable legal framework for international nuclear energy projects. This legal framework has the effect of providing United States nuclear suppliers with insurance for liability that arises out of any covered incident outside the United States that is not a Price-Anderson incident, and that without the Convention would be unlimited. While acknowledging the benefits of the Convention and the express mandate of section 934 that U.S. nuclear suppliers should pay the United States' contributions under the Convention, several commenters nonetheless expressed concerns about the policy of imposing this financial burden on nuclear suppliers and the ability of the Department to allocate the cost among suppliers in a defensible and equitable manner. Commenters noted that the financial burden imposed on the nuclear supplier industry might negatively impact the competitiveness of the United States nuclear industry in international markets, contrary to the President's goals in the National Export Initiative. In that regard, the comment was made that DOE should recommend to Congress that the Act be amended to eliminate the burden on industry and the rulemaking deferred to allow DOE to conduct in-depth discussions with industry to evaluate the impact on domestic jobs and gather data and information to support a risk-based allocation system. Many commenters noted that current information and data was lacking on how to assess nuclear risks for the development of a risk-based formula, and/or to support the operation of such a formula in the event of an incident.

In response, the Department notes that section 934 requires the Department develop and implement regulations to establish the retrospective risk pooling program to be funded by U.S. nuclear suppliers. Moreover, recent events with the tsunami and earthquake affecting nuclear reactors in Fukushima, Japan underscore the importance of a robust legal system to promptly and meaningfully compensate victims of nuclear incidents and provide consistent rules for dealing with legal liability.[6] The Department believes that sufficient information and data are available to develop a formula and that a data collection system can be implemented to support the operation of such a formula if it needs to be used in the future. Nonetheless, the Department seeks additional commentary and specific information from the nuclear industry on the potential impacts to U.S. competitiveness in the nuclear export arena and the President's National Export Initiative. The Department is also interested in receiving comment on which alternative regulation, the first or the second, is better suited to mitigate the impacts, if any, on United States' competitiveness in the nuclear export arena.

The Department has proposed two alternative methods of calculating the retrospective premium payment to provide the public with a set of options and a range of alternatives to review and assess. As explained in greater detail in the following sections, the proposed regulation addresses many of the commenters' concerns and adopts many of the safeguards suggested, while fulfilling DOE's obligation to implement section 934.

Section 951.3—Definitions

The terms that are defined in the Act are so defined in this proposed regulation; however, DOE has added other terms as necessary to establish the retrospective risk pooling program and the risk-informed assessment formula. The following describes specific terms (not in alphabetical order) key to understanding the overall structure and

[6] In response to the accident at TEPCO's Fukushima Daiichi Nuclear Power Station, the IAEA issued its Action Plan on Nuclear Safety (Plan), approved by the Board of Governors and endorsed by the IAEA General Conference in September 2011, calling upon its members to strengthen nuclear safety through measures proposed in the Plan. *http://ola.iaea.org/ola/documents/ActionPlan.pdf.* One of those measures is for members to support efforts to establish and promote a global nuclear liability regime, such as the CSC.

operation of the retrospective risk pooling program under either Alternative 1 or 2; other terms are explained in connection with the subpart to which they specifically apply.

Nuclear supplier. This term is defined in the Act, and would be adopted verbatim in the regulation. The term nuclear supplier as defined in the Act means a covered person (or a successor in interest of a covered person) that—(A) supplies facilities, equipment, fuel, services, or technology pertaining to the design, construction, operation, or decommissioning of a covered installation; or (B) transports nuclear materials that could result in a covered incident. Section 934(b)(7). In light of the statutory definition which includes a successor in interest to a covered person, the term ''nuclear supplier'' would encompass an entity that merged with another having reportable transactions. Therefore, the merged company, as successor in interest, would also have reportable transactions. The Department sought comment in the NOI on whether further interpretation of this definition was necessary, noting its importance in the regulatory scheme but that it is ''potentially very broad in scope, complex, and subject to interpretation.'' 75 FR 43946–43947, 43949. The Department received several comments echoing the importance of this term to the operation of the Act, the need for clarification of the term, and provisions excluding certain nuclear suppliers from operation of the Act. In this proposed rule, the Department maintains the statutory definition of nuclear supplier, and addresses any uncertainty regarding inclusion or exclusion of a nuclear supplier from the retrospective risk pooling program through other provisions in the regulation, explained below.

Covered nuclear supplier and *reportable transaction.* To address the concerns of commenters regarding the definition of nuclear supplier and to add certainty to the rule, the proposed rule introduces the concept of a ''covered nuclear supplier.'' A covered nuclear supplier is a nuclear supplier (as defined in the Act) whose goods or services, if supplied in the United States, would be required to comply with the requirements of 10 CFR part 21. Part 21 requires suppliers of basic components to any facility or activity licensed or otherwise regulated by the NRC to report any defects or noncompliance with their product. This NRC regulation acts as a safeguard to ensure that basic components of a nuclear facility are designed and manufactured to operate as intended, in a safe manner and without defect. If a good or service is subject to the part 21 requirements, it is more likely to be safety-related, or may be dedicated as safety-related by the NRC licensee if used in a safety-related function, and therefore provide the basis for a claim against its supplier in the event of a nuclear incident. Conversely, if a good or service is not subject to the part 21 requirements, it is less likely to provide a basis for a claim. This method of differentiating nuclear items is clear and certain within the nuclear industry, and provides a reasonable basis for allocating risk among nuclear suppliers.

As explained in the NOI, the Department believes that the statutory risk factors to be considered in developing the risk-informed assessment formula (see section 934(e)(2)(C)(i)) indicate that only nuclear suppliers of goods or services most likely to be exposed to significant potential liability in the event of a covered incident would be included in the retrospective risk pooling program. 75 FR 43950. Those types of suppliers are best represented as the suppliers of goods or services specifically intended for use in structures, systems, and components related to safety at a nuclear installation. 75 FR 43951. Further, the concept of limiting the application of the rule to only those suppliers of items related to safety would operate to eliminate from consideration nuclear suppliers of goods or services that do not contribute significantly to the risk of a nuclear incident in accordance with the exclusion factors in subsection 934(e)(2)(C)(ii)(I), such as classes of goods and services with negligible risk and goods and services not intended specifically for use in a nuclear installation in accordance with subsection 934(e)(2)(C)(ii)(I)(aa), (bb). 75 FR 43950–43951. The majority of the commenters agreed that this approach would be a reasonable implementation of the statutory risk factors, specifically, the direction to DOE to consider factors such as the nature and intended purpose of the goods and services (934(e)(2)(C)(i)(I)) and the hazards associated with such goods and services should they fail to achieve the intended purposes (934(e)(2)(C)(i)(III)).

In addition, this approach provides an objective benchmark for nuclear suppliers. Nuclear suppliers whose goods and services, if supplied in the United States, would be subject to the NRC's part 21 requirements can be certain what goods or services they supply abroad are subject to reporting requirements of the proposed rule. As discussed further below, only covered nuclear suppliers (or their successors in interest) are required to report to the Department their prior and annual reportable transactions for purposes of applying the risk-informed assessment formula in the event of a request for funds. Not all transactions by a covered nuclear supplier are a reportable transaction, however. A ''reportable transaction'' means any transaction by a covered nuclear supplier involving the supply of items specified in appendices A and B (Alternative 1) or the items identified in the definition of ''reportable transaction'' in section 951.3 (Alternative 2). Accordingly, an entity may be a nuclear supplier as defined under the Act and regulation, but only subject to the reporting requirements of the proposed rule if it is a covered nuclear supplier engaged in reportable transactions as defined in the regulation. Further, a nuclear supplier may have reportable transactions, but would only be assessed a risk premium payment on the basis of its ''covered transactions.''

The Department seeks comment on whether NRC's part 21 regulations, or some other regulatory requirement or concept such as the quality assurance requirements in 10 CFR part 50, appendix B, are appropriate criteria to determine which nuclear suppliers should be defined as a covered nuclear supplier.

Covered transaction and *final nuclear supplier.* A ''covered transaction'' is a reportable transaction where a nuclear supplier is the final nuclear supplier to a covered installation. The term ''final nuclear supplier'' is defined in the proposed rule as: the nuclear supplier that obtains, where required, an NRC general or specific license under 10 CFR part 110, Department of Commerce export license under 15 CFR part 734, or DOE authorization under 10 CFR part 810 for the export of the item(s) involved in a reportable transaction. The terms ''covered transaction'' and ''final nuclear supplier'' are proposed to identify which nuclear suppliers are obligated to pay a risk premium with respect to what type of good or service.

The Department received numerous comments on the dynamic nature of the nuclear industry both domestically and abroad, and the difficulty many suppliers would have in tracking with certainty whether their good or service were supplied to a foreign nuclear installation. For example, many commenters noted that their goods may be incorporated into other nuclear goods which ultimately may or may not be exported, and that it is impossible to ascertain whether their good has been supplied to a covered installation for

reporting purposes or otherwise. Commenters argued against imputing to nuclear suppliers an intent to export a good or service when none can be shown or known, and argued for certainty in identifying the pool of nuclear suppliers that are supplying goods or services to foreign nuclear installations. One commenter suggested using export licenses, authorizations, or other such approvals as criteria.

Recognizing these concerns on a practical and policy level, the Department is proposing that only final nuclear suppliers, *i.e.,* the nuclear suppliers that obtain the applicable export license or authorization, be the nuclear supplier covered by the retrospective risk pooling program. A final nuclear supplier is proposed to be defined in effect as a covered person who obtains or relies on licenses from the Department of Commerce under 15 CFR part 734 or NRC under 10 CFR part 110, or authorizations from DOE under 10 CFR part 810 to manufacture, provide or produce facilities, equipment, fuel or services specifically for use in covered installations outside the United States. Only the final nuclear supplier can report with certainty on the timing, destination, value and quantity of exported goods or services. This information is essential in developing and implementing any risk-informed assessment formula. The Department believes that this is a fair and equitable approach to allocate risk among United States nuclear suppliers. The final nuclear supplier will have the ability, if desired, to negotiate with its suppliers to recuperate any potential costs or liability it will bear under the proposed rule. Such cost and risk allocation among nuclear suppliers is best left to the industry to manage on its own terms as a business arrangement, rather than by the Department through regulation. Also, the final nuclear supplier is the person most identifiable to the covered installation at which the nuclear incident occurs, and therefore the person most likely to be subject to potential liability in the event of a covered incident. Precisely because of this fact, it is the final nuclear supplier that is most in need of and benefitted by the protections of the Convention. Limiting the transactions covered by the regulation to those of a final nuclear supplier represents the most reasonable, fair and manageable approach available to the Department and responds to concerns expressed by commenters on the NOI.

In sum, under either Alternative 1 or 2, a nuclear supplier would be part of the retrospective risk pooling program and obligated to make a risk premium payment if the nuclear supplier: (1) Supplied goods or services specified in the appendices (Alternative 1) or included in the nuclear sector (Alternative 2) that, if supplied in the United States, would be subject to the requirements of 10 CFR part 21; (2) obtained the necessary export licenses or authorizations to supply those goods or services; and (3) supplied those goods or services to nuclear installations that are covered by the CSC, *i.e.,* covered installations.

Covered installation. The Department proposes to define the term ''covered installation'' as it is in the Act. A ''covered installation'' is a nuclear installation at which the occurrence of a nuclear incident could result in a request for funds under the Convention. Such a nuclear incident would be an incident that exceeds the amount available under the first tier of compensation, equivalent to roughly 300 million SDRs, or about $460 million, and occurred in a State that is a Contracting Party (CSC member State) to the Convention. (If the incident were to occur in the United States, the first tier of compensation would be covered by the Price-Anderson Act.) Several commenters noted that the rule should make clear that the term ''covered installation'' means only nuclear installations in a CSC member State. One commenter noted that the legislative history of section 934 suggests the Department is not limited to only countries that have ratified the Convention, but should also include countries that have signed the Convention or are likely to join in a reasonable period of time. After considering these comments, the Department is proposing that a covered installation is a nuclear installation in a CSC member State at the time of the nuclear incident for which the contribution to the international supplementary fund is made. While flexibility and breadth of application may be desirable in some respects, in the end the United States would only be called upon to contribute to a nuclear incident in a CSC member State, and therefore the risk premium—and potential liability avoided by operation of the Convention—should be calculated based upon transactions with nuclear installations only in CSC member States.

Comments also were received that the Convention definition of ''nuclear installation'' was not sufficiently explicit to allow nuclear suppliers to identify the covered installations outside the U.S. to which the Convention would apply. It was suggested that DOE post a list of those covered installations in member countries, so that only those facilities would be provided Convention protection. The Convention provides for a list of nuclear installations at Article VIII, which requires that each Contracting State communicate to the Depositary a complete listing of all nuclear installations referred to in Article IV.3, meaning a list of all nuclear reactor installations in the member country. Further, the Convention definition is sufficiently explicit as to the type of facilities that would qualify for coverage, and CSC member States would be a matter of public record (*http://www.iaea.org/Publications/Documents/Conventions/supcomp_status.pdf*), such that U.S. nuclear suppliers are reasonably able to determine the type of facility at which a nuclear incident may result in a request for funds. The Department does not believe that another list is necessary or appropriate to implement the rule but seeks comment from the public on this suggestion.

Nuclear installation. ''Nuclear installation'' is not defined in the Act; however, as noted above, it is defined in the Convention. The Convention has differing definitions of ''nuclear installation;'' the applicable definition depends upon the installation state where the incident occurs and the nuclear liability instrument in effect in that State, *e.g.,* the Vienna or Paris Convention, or, if a Contracting Party does not belong to either of those Conventions, then the definition in Article 1.1(b) of the Annex to the Convention (Annex). For the United States, there is an additional option for defining a nuclear installation under Annex Article 2.3. As noted previously in the NOI, DOE intends to apply the Annex Article 2.3 definition of ''nuclear installation'' for covered incidents within the United States. However, for covered incidents outside the United States, the Department would apply the Annex Article 1.1(b) definition as the retrospective risk pooling program applies only to covered incidents outside the United States. Thus, the appropriate reference point for the type of nuclear installation that constitutes a covered installation would be the Paris Convention, Vienna Convention or Annex Article 1.1(b), depending on whether the Paris Convention, Vienna Convention, or the Annex was the applicable law for the country where the nuclear incident occurred. As a practical matter, these definitions are essentially the same.

In this proposed rule, the definition of ''nuclear installation'' closely mirrors that in Article 1.1(b) of the Annex. Some

revisions were made to the definition for simplicity and clarity, *e.g.,* the word ''factory'' used in the Annex, was replaced with the somewhat broader or more commonly used phrase ''facility or plant'' to ensure all nuclear installations are covered. More simply put, the Department interprets the definition of ''nuclear installation'' in the Convention, and in the proposed rule, to mean the following types of nuclear installations: civilian nuclear power reactors, civilian nuclear research or test reactors, nuclear fuel fabrication facilities, spent or used nuclear fuel reprocessing facilities, uranium enrichment facilities, and storage facilities for ''nuclear materials'' as defined in the Convention, which would include storage facilities for spent nuclear fuel and radioactive wastes (except for storage of nuclear materials incidental to the transport of such materials). In addition, as the definition provides, where there are several nuclear installations of one operator at a single site, for example, a single site with multiple reactor units, the installation state would determine whether this represents a single nuclear installation or multiple nuclear installations. In the case of the United States as the Installation State, a single site with multiple reactor units would be considered a single nuclear installation.

Commenters argued for the exclusion of certain nuclear facilities from the definition of a ''nuclear installation,'' and the Department independently considered what installations properly fit within the definition of a nuclear installation. One commenter noted that DOE should expressly exclude from the definition of ''covered installation'' nuclear waste disposal facilities, *e.g.,* low-level waste disposal facilities, on the basis that disposal facilities are distinct from storage facilities, and only the latter facilities are included in the Convention definition of a ''nuclear installation.'' Other commenters from the uranium mining, milling and conversion industries noted that they are not nuclear suppliers under the Act because their products and services—natural uranium concentrates and conversion of natural uranium to uranium hexaflouride—are not nuclear ''fuel'' and require several intervening and separate actions to be transformed into a form that can be used as fuel for a reactor. Commentors also noted that natural uranium as mined or converted into uranium hexafluoride presents negligible risk to a covered facility, and could not reasonably be considered a proximate cause or contribution to a nuclear incident giving rise to a call for funds under the Convention. Further, the Department notes that natural uranium is excluded from the definitions in the Convention of ''nuclear fuel'' and ''nuclear material''.

Based on the foregoing, the Department concludes that the definition of ''nuclear installation'' does not include radioactive waste disposal facilities or uranium mining, milling and conversion facilities. Uranium mining, milling and conversion facilities do not fall within the definition of ''nuclear installation'' as they do not involve the use of nuclear fuel or nuclear material as defined in the Convention. In addition, DOE agrees that suppliers of natural or depleted uranium or uranium conversion services are not suppliers of fuel and thus not nuclear suppliers that would be subject to the requirements of this proposed rule. Finally, we agree that the definition of ''nuclear installation'' does not cover radioactive waste disposal facilities which are distinct from storage facilities. NRC treats storage and disposal activities under separate regulations (*e.g.,* 10 CFR parts 60, 61, and 72), as does DOE in regard to requirements for its activities (*e.g.,* DOE Manual 435.1, where disposal is defined as ''emplacement of waste in a manner that ensures protection from the public, workers, and the environment with no intent of retrieval and that requires deliberate action to regain access to the waste'' and storage means ''the holding of radioactive waste for a temporary period, at the end of which the waste is treated, disposed of, or stored elsewhere.''). This distinction is also recognized on the international level, in the Joint Convention on Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, to which the United States is a party, in the differing definition and treatment of those concepts in practice. Accordingly, radioactive waste disposal facilities are not a covered installation, and suppliers of goods or services to radioactive disposal facilities are not subject to the requirements of this proposed rule.

Nuclear material. The Department defines ''nuclear material'' as it is defined in the Convention. The Convention, Annex Article 1, includes a definition of ''nuclear material'' that specifies nuclear material means nuclear fuel, other than natural uranium and depleted uranium, capable of producing energy by a self-sustaining chain process of nuclear fission outside a nuclear reactor, and radioactive products or waste. ''Radioactive products or waste'' has its own definition in the Convention, which is incorporated verbatim in this proposed rule. ''Radioactive products or waste'' are defined as radioactive material produced in, or any material made radioactive by exposure to the radiation incidental to the production or utilization of nuclear fuel. However, radioactive material does not include radioisotopes, which have been fabricated and are usable in any scientific, medical, agricultural, commercial or industrial purpose.

The Department interprets the Convention definition of ''nuclear material'' to include nuclear materials such as enriched uranium, nuclear fuel, irradiated (spent) nuclear fuel, and radioactive wastes, and to exclude as nuclear materials natural uranium, depleted uranium, and radioisotopes in usable form.

Covered person. The definition of ''covered person'' is significant in that a nuclear supplier, as defined in the Act, is a covered person or a successor in interest to a covered person. The Department defines ''covered person'' as it is defined in the Act. A covered person includes any United States person, or any individual or entity (including an agency or instrumentality of a foreign country) that is located in the United States or carries out an activity in the United States. DOE interprets this definition broadly. For example, a foreign company that carries out any activity in the United States and exports from the United States nuclear goods or services would be a covered person. On the other hand, an example of an entity that is not a covered person would be a U.S. company that provides goods or services to a foreign nuclear installation but does so under contract to the United States government. The statutory definition of ''covered person'' excludes ''(i) the United States; or (ii) any agency or instrumentality of the United States.'' Section 934(b)(6)((B). Under such circumstances, a U.S. company would not be considered a covered person for purposes of that activity and therefore would not be included within the retrospective risk pooling program. DOE notes that a company may provide goods and services to a foreign installation both on its own account (*i.e.,* not for the United States government), and for the United States government; such company would be considered a ''covered person'' for its private transactions only.

Subpart B—Retrospective Risk Pooling Program

Alternatives 1 and 2 are described separately in the following discussion of Subpart B, with the exception of the role

of the Department and the retrospective risk premium payment cap. Both of these topics are presented in the discussion of Alternative 1 but are the same under both alternatives.[7] The role of the Department is set forth at section 951.4 under both alternatives, while the retrospective risk premium payment cap is set forth at section 951.10 in Alternative 1 and section 951.16 in Alternative 2. As noted previously, Alternative 1 would establish a risk-assessment formula based on goods or services provided by a nuclear supplier, while Alternative 2 would establish a risk-assessment formula based on nuclear sectors.

Alternative 1—Risk-Informed Assessment Formula by Nuclear Goods and Services

Section 951.4—Role of the Department

Section 951.4 provides for the role of the Department in the event there is a request of the United States for funds under the Convention. The amount requested of the United States, that is, the contingent cost, will be based on the rules and formula in the Convention for allocating costs among CSC member States (Article IV). The contingent cost will be a fixed amount, *e.g.,* $150 million.[8] DOE's role is to allocate that amount among the U.S. nuclear suppliers based upon the risk-informed assessment formula set forth in the rule.

Within 60 days of a request for funds under the Convention, the Department will calculate the retrospective premium payment owed by each nuclear supplier based upon the risk-informed assessment formula. Notification to nuclear suppliers will be provided in the **Federal Register**. Payment requirements for nuclear suppliers are set forth in subpart C of this proposed rule.

Section 951.5—Retrospective Premium Payment

A nuclear supplier's retrospective premium payment will be calculated based on the nuclear supplier's share of the contingent cost owed by the United States under the Convention. Each nuclear supplier will be assessed a pro-rata share of the costs based on its share of the risk. The risk share, which is a function of the supplier's risk exposure, is expressed as a percentage of the contingent cost, so that the retrospective premium for each nuclear supplier is its risk share (*e.g.,* 2%) multiplied by the contingent cost (*e.g.,* $150 million), resulting in the amount of the retrospective premium payment (*e.g.,* $3 million).[9] The ''risk'' that is the subject of this risk-informed assessment formula, and the basis for the risk premium payment, is the risk that a nuclear supplier's goods or services would provide the basis for a claim against the supplier in the event of a nuclear incident at a covered installation that would give rise to a call for funds under the Convention.

Section 951.6—Risk Share, Section 951.7—Risk Exposure, and Section 951.8—Aggregate Risk Exposure

A nuclear supplier's risk share is their relative risk exposure compared to the aggregate risk exposure of all U.S. nuclear suppliers. Based upon the information gathered under subpart D for reporting transactions, the Department would calculate the amount of each nuclear supplier's risk exposure and the overall or aggregate risk exposure of U.S. nuclear suppliers. The aggregate risk exposure is simply the sum of all nuclear suppliers' risk exposure. The risk exposure of a nuclear supplier is the adjusted value of all covered transactions of that nuclear supplier, weighted as either 2 (items listed in appendix A) or 1 (items listed in appendix B) in accordance with the risk associated with the goods or services provided. Appendix A contains a list of primary nuclear items, meaning items with a greater likelihood of contributing to a nuclear incident resulting in a call for funds, and therefore such items are given twice the weight as items listed in appendix B. Appendix B contains a list of secondary nuclear items, meaning items with less likelihood of contributing to a nuclear incident resulting in a call for funds. Each nuclear supplier's risk exposure is calculated as the sum of the adjusted value of all their covered transactions, appropriately weighted. The aggregate risk exposure is the sum of all nuclear suppliers' risk exposures. A nuclear supplier's risk share is then calculated, *i.e.,* the nuclear supplier's risk exposure divided by the aggregate risk exposure.

The most important variable in the equation is the nuclear suppliers' covered transactions. A covered transaction under Alternative 1 is defined as ''any reportable transaction by which a nuclear supplier is the final nuclear supplier to provide any of the items listed in appendix A or B for use in the design, construction, operation or decommissioning of any covered installation or in the transportation of material to or from a covered installation.'' Section 951.3. The definition of covered transaction provides important indicators of what nuclear suppliers will have covered transactions (only those that are reportable and made by final nuclear suppliers).

First, the transactions used in the risk-informed assessment formula must be reportable transactions. Reportable transactions are transactions of a ''covered nuclear supplier,'' engaged in after a certain date as specified in the rule, to provide any of the items listed in the appendices for use in the design, construction, operation, or decommissioning of any nuclear installation outside the United States or in the transportation outside the United States of nuclear material to or from a nuclear installation. Accordingly, not every transaction of a nuclear supplier is a reportable transaction. Reportable transactions are those transactions: (1) Made by a covered nuclear supplier, meaning a nuclear supplier that supplies goods or services, if supplied in the United States, that would be subject to the requirements of 10 CFR part 21; (2) occurring after 1959 (*i.e.,* starting January 1, 1960) for items listed in appendix A, and after 2007 (*i.e.,* starting January 1, 2008) for items listed in appendix B; (3) for items listed in the appendices, rather than all nuclear goods or services. The transactions must also be for items used in: (1) Nuclear installations outside the United States, so that nuclear items supplied to domestic nuclear installations are not included; or (2) the transportation outside the United States of nuclear material to or from a nuclear installation, so that transport transactions are limited to transport of nuclear material outside the United States, and between nuclear installations outside the United States.

Second, the transactions used in the risk assessment formula must be made by a ''final nuclear supplier.'' As previously explained, many commenters noted that it can be very

[7] DOE notes that Subparts A (except for the definitions of covered transaction and reportable transaction), C and D, are also the same for Alternative 1 and 2.

[8] The numbers provided in the text and as parentheticals are examples only, and not intended to represent an actual case.

[9] The numbers provided in the text and as parentheticals are examples only, and not intended to represent an actual case. The following hypothetical amounts illustrate how the formula would work, where it is assumed that: contingent cost = $150 million; aggregate risk exposure = $500 million; nuclear supplier's covered transactions = $4 million from Appendix A, and $2 million from Appendix B.

Retrospective Premium Payment = risk share [.02] × contingent cost [$150,000,000] = $3,000,000

Risk share = risk exposure [$10,000,000]/ aggregate risk exposure [$500,000,000] = .02 or 2%

Risk exposure = (value of covered transactions from Appendix A × 2) [$4,000,000 x 2] + (value of covered transactions from Appendix B × 1) [$2,000,000 × 1] = $8,000,000 + $2,000,000 = $10,000,000

difficult to determine whether a nuclear item has been exported and used in a foreign nuclear installation, as many items are sold directly to other entities within the United States, who may export them as is or in combination with other items, and their ultimate end use destination is not known. On the other hand, the entity that exports the nuclear item (*i.e.,* the final nuclear supplier) whether as a single item or in combination with other items, will know that the item is being exported for use in a nuclear installation outside the United States. By limiting covered transactions to those involving final nuclear suppliers, the rule operates to encompass those nuclear suppliers for which records can be reliably kept and maintained on nuclear items supplied to foreign nuclear installations, or nuclear materials transported between foreign nuclear installations. Further, this approach addresses the concern expressed by some commenters that the rule should be clear that it applies only to suppliers of goods or services to foreign installations, and does not apply to suppliers of goods or services solely to domestic installations.

Further, the time period of reference in calculating the risk premium is the period starting from the date of reportable transactions (either after 2007 or 1959 for certain suppliers) until the date of the nuclear incident. Several commenters noted that the period of assessment should be on a rolling basis, for example a five-year period, prior to the nuclear incident. The Department believes this formulation may be too restrictive and fail to cover nuclear suppliers whose goods or services may have contributed to a nuclear incident and therefore should be liable for their share of the contingent costs. Except for nuclear suppliers of items in appendix A (and suppliers to the facility sector in Alternative 2, discussed below), all other nuclear suppliers would have reportable transactions after 2007, when section 934 was enacted. Suppliers of items in appendix A would have reportable transactions after 1959, when many of the foreign nuclear installations that would be covered installations under the CSC were constructed and began operations. Development of a risk-assessment formula equitable to all nuclear suppliers requires looking back to 1960 for nuclear suppliers who would have been the most likely to have supplied goods or services to nuclear installations at which a nuclear incident may occur, and who would benefit from the protections of the Convention. To do otherwise would improperly place the majority of the burden of the contingent costs on nuclear suppliers with more recent transactions that may have little or no relation back to those nuclear installations. Nonetheless, the Department recognizes that recordkeeping back to 1960 may be challenging, and seeks comment from the public on the probability and feasibility of collecting information from that timeframe.

In developing the risk-informed assessment formula, the Department considered the risk factors set forth in section 934 along with its own experience and expertise to arrive at a quantifiable formula and develop the appendices to the rule. Section 934(e)(2)(C). As explained in the NOI, DOE interpreted these risk factors to support an approach that focuses on goods or services specifically intended for use in structures, systems, and components important to safety at a nuclear installation as the goods and services to be ranked and used in calculating the risk premium. 75 FR 43950–43951. Following this approach, the appendices identify particular nuclear goods and services and assigns to those goods or services a risk rating or ranking—primary or secondary—and a corresponding weight—2 or 1—that is then multiplied by the adjusted value of the goods or services exported and added together to equal a nuclear supplier's risk exposure.

The Department received many comments on how it must develop additional information to adequately assess and assign the risk factors. Few of the commenters, however, provided explicit recommendations on risk ratings for specific categories or types of nuclear goods or services. Most commenters expressed doubt that the Department could objectively establish a risk ranking for specific nuclear goods and services with sufficient support to provide a credible basis for the rule. While the Department acknowledges the difficulty of the task, the Department believes it has proposed a rule that fulfills the statutory mandate in an equitable manner.

The Department believes the items defined in appendix A are the primary components, equipment, systems, and structures that, by their design, are intended to protect the public health and safety from operational events and plant transients (design basis or beyond design basis events) that could cause nuclear incidents within the purview of the Convention. These items were drawn from DOE's knowledge and experience in the history and operation of various nuclear facilities, as well as the NRC regulatory structure and emphasis on the importance of safety in nuclear operations. In addition, the Department recognizes that other nuclear items identified in appendix B may also cause a covered event but considers the likelihood and severity of those events to be secondary to, or of lower risk, than, those items in appendix A. Hence, the items are weighted differently to reflect this risk allocation. The Department seeks public input on the risk sharing classification of covered items in the appendices, and suggestions for additions or deletions from the list and the supporting bases for those suggestions as available.

Section 951.9—Small Nuclear Supplier Exclusion

Section 951.9 proposes an exclusion from payment of the retrospective risk premium for small nuclear suppliers. All commenters supported such an exclusion, and section 934 expressly provides for DOE to exclude nuclear suppliers with a de minimis share of the contingent costs. 934(e)(2)(C)(ii). In this proposed rule, the Department proposes two alternatives for determining whether a nuclear supplier is excluded from payment as a ''small'' supplier. First, DOE proposes to determine a small nuclear supplier based on an amount of risk exposure that is ''de minimis,'' such as $1 million. One commentor suggested nuclear suppliers with less than $1 million in annual total sales to covered nuclear installations may be considered ''de minimis.'' DOE seeks public comment on this and other potential amounts. The amount established in the rule must take into account the consideration that it not be set too low, as risk exposure may be based on many years of transactions, or too high, as the intent is to focus the application of the rule on nuclear suppliers that are the most likely to be subject to claims for damage resulting from a nuclear incident giving rise to nuclear damage in excess of 300 million SDRs. In the alternative, the Department proposes excluding all suppliers that qualify as ''a small business'' in accordance with size standards established by the Small Business Administration (SBA), on the basis that such suppliers are unlikely to be subject to claims for damage. The Department welcomes additional comment and feedback from the public on what dollar amount or other criterion, such as classification as a ''small business'' under SBA size standards, is reasonable to use for the exclusion of small nuclear suppliers.

Section 951.10—Retrospective Premium Payment Cap

Section 951.10 proposes a cap on the retrospective premium payment for any one nuclear supplier, to be specified in the rule as a specific dollar limit or a percentage of the contingent cost. All commenters supported a cap on premiums, arguing that a cap would provide predictability to the program thereby allowing nuclear suppliers to plan and potentially insure themselves against the risk of a premium payment in the future. Also, many commenters believed a cap was a means to equitably apportion the contingent costs and insure no one supplier was unduly burdened with the majority of the cost.

In response to these comments, the Department is proposing to include such a cap in the rule. DOE seeks comment on the amount or percentage of the contingent cost that is appropriate as a cap on any one supplier's premium payment. As a basis for additional comment from the public, the Department is considering amounts such as 5%, or 25%, of the contingent cost, or a specific dollar amount, *e.g.,* $25,000,000, as suggested by several commenters.

While the Department supports a cap, it is required that the United States government be paid in full by nuclear suppliers the same amount as the United States government is obligated to contribute as a CSC party under the Convention. Accordingly, the proposed rule provides for assessing additional premium payments from the nuclear suppliers that have not reached the cap on payments in the event there is a shortfall in payments from suppliers with respect to the United States' obligation. The additional payments would be allocated on a pro rata basis, consistent with each nuclear supplier's share of risk as calculated under the rule, and shall operate until a nuclear supplier reaches the cap or the shortfall is met, whichever occurs first. In the unlikely event this process results in each nuclear supplier reaching the cap on payments and the shortfall is not met, then all nuclear suppliers will be assessed a pro rata share of the remaining shortfall until funds in the amount of the United States' contribution have been paid to the Treasury. The Department welcomes additional comment and feedback from the public on the process for ensuring the United States is fully paid by nuclear suppliers the amount it is obligated to contribute under the Convention.

Alternative 2—Risk-Informed Assessment Formula by Nuclear Sector

Section 951.5—Nuclear Supplier Sectors

Section 951.5 groups nuclear suppliers in accordance with the sector of the nuclear industry to which they provide goods or services. This approach groups suppliers based on the commonality of the type of goods or services they supply and the risk that those goods or services would contribute to a nuclear incident. The Department believes categorizing nuclear suppliers in this manner is a useful and equitable mechanism to reflect the allocation of risk among nuclear suppliers. Also, this approach is consistent with the concept suggested by several commenters that DOE assign risk by looking at the stages of the nuclear fuel cycle, where each stage would be grouped in accordance with its relative risk as a contributor to a nuclear incident. The nuclear supplier sectors are: (1) Facility; (2) equipment and technology; (3) nuclear material and nuclear material transportation; and (4) services. The Department believes it has defined nuclear sectors in a reasonable and workable manner but welcomes suggestions from the public on other ways to define nuclear sectors, *e.g.,* defining the sectors based upon the stages of the fuel cycle or by installation type.

As described in the rule, the first sector is the facility sector, which encompasses nuclear suppliers that are the lead suppliers involved in the development and deployment of nuclear installations. The term ''lead supplier'' is defined in the proposed rule as a nuclear supplier whose adjusted value of reportable transactions for the period from January 1, 1960 through 2007 exceeds $500 million, or some other amount to be determined by DOE based on consideration of public comment. By establishing as the benchmark for defining a lead nuclear supplier a dollar value of reportable transactions of that supplier over the period 1960 through 2007, the Department intends to capture in this sector those suppliers that could have been characterized as the primary supplier to a nuclear installation. For example, many of the reactors in existence today were constructed and installed several decades ago and, at that time, there was a single nuclear supplier that led in the design, component, equipment and technology supply of the reactor. In essence, the lead supplier is the nuclear supplier that supplied the nuclear installation as a whole, and not merely individual components or parts that make up the whole.

The Department recognizes that there has been a shift in the nuclear industry, and current business arrangements among suppliers and nuclear installation operators are not necessarily structured as in the past. For this reason, the facility sector is backward looking (that is, looking back from 2007 when section 934 was enacted), and only comprises those nuclear suppliers that qualify as a lead supplier of a nuclear installation for the period 1960 through 2007. Nuclear suppliers that fit within the facility sector would only report transactions for the period from January 1, 1960 through December 31, 2007; for transactions after 2007 (the year of enactment) it is expected that nuclear suppliers would fit into one or more of the other nuclear sectors. Limiting the time period for operation of the facility sector reflects the structure of the nuclear industry in the past and present, while allocating the costs equitably among nuclear suppliers based on the likelihood their goods or service would contribute to a nuclear incident occurring at a nuclear installation.

Moreover, this approach is reasonable in terms of recordkeeping and transaction reporting. It is less likely that a nuclear supplier, other than the lead supplier, would have records of their transactions dating back to the initial operation of most of the nuclear installations in existence today—precisely the installations at which a nuclear incident may occur. Therefore, the lead suppliers of those installations should be assessed a proportionate share of the contingent costs. Further, it is most likely that the lead supplier to a nuclear installation built decades ago would also be the final nuclear supplier, *i.e.,* the nuclear supplier that obtained the necessary licenses and/or authorizations for the export of the nuclear goods and services comprising the nuclear installation. In sum, the facility sector represents the group of nuclear suppliers operating in the 1960 through 2007 time period, a period in which most nuclear installations were developed and deployed and were in large part supplied by a single nuclear supplier of significant resources and expertise, and for which records of the supply transactions would exist today and form an equitable basis to allocate risk and costs among them. The Department seeks comment on what other descriptors of a lead supplier would be appropriate to be included in the proposed rule to further clarify the definition of facility sector nuclear suppliers.

The remaining three nuclear sectors are the equipment and technology sector, the nuclear material and nuclear material transportation sector, and the nuclear services sector. These sectors cover only reportable transactions of a nuclear supplier occurring from January 1, 2008 onward. These sectors reflect the more current business structure of the nuclear supplier industry, with suppliers specializing in specific goods or services and managing risks and costs among the suppliers as part of their business arrangement. The equipment and technology sector encompasses nuclear suppliers of equipment, components and technology used in a nuclear installation. This sector captures the nuclear suppliers that provide the multitude of equipment, component parts and technology to a nuclear installation, but would not be a lead supplier. The nuclear material and nuclear material transportation sector encompasses suppliers of nuclear material to a nuclear installation and the suppliers that transport nuclear material between installations. This sector captures suppliers such as those that furnish fresh fuel to a reactor, or irradiated nuclear fuel to a reprocessing facility, as well as the suppliers that provide transportation of fresh fuel or irradiated fuel between nuclear installations. The nuclear services sector encompasses suppliers of services to a nuclear installation for the design, construction, operation or decommissioning of a nuclear installation. This sector captures suppliers of services to a nuclear installation, such as operating services, and architecture, engineering and construction services.

DOE notes that although there may be overlap among these three sectors (*e.g.,* a nuclear supplier may supply both nuclear equipment and services), each sector was developed because it can be reasonably distinguished from the other sectors in terms of the nuclear items supplied and the relative risk of those items. As previously noted, the sectors are based on the expectation that the nuclear suppliers falling within each sector would be similarly situated in terms of the relative risk of their goods or services contributing to a claim for damages related to a covered incident, and their capacity to have reliable and extant records of their transactions to support an allocation of cost among them. If a supplier provides goods or services to more than one sector, the supplier would calculate their risk premium payment for covered transactions within each sector, with the total payment the sum of the premium for each sector.

The Department believes the four nuclear sectors fairly represent the nuclear supplier industry as a whole and the suppliers to the nuclear industry that should be part of the retrospective risk pooling program. The Department also believes the nuclear sectors are similar to an approach proposed by some commenters to categorize suppliers in relation to their place within the fuel cycle (*e.g.* front-end or back-end suppliers), but welcomes additional comment from the nuclear industry on whether this approach is appropriately structured and alternative suggestions.

Section 951.6—Retrospective Premium Payment

A nuclear supplier's retrospective premium payment will be calculated based on the nuclear supplier's risk share of the contingent costs allocated to the nuclear sector in which the supplier is grouped. Each nuclear supplier will be assessed a pro-rata share of the allocated costs within their nuclear sector based on their share of risk within that sector. The risk share by sector is expressed as a percentage, and the allocated cost is a fixed number, so that the retrospective premium for each nuclear supplier is their risk share by sector (*e.g.,* 4%) multiplied by the allocated cost by sector (*e.g.,* $75 million), resulting in the amount of the retrospective premium payment (*e.g.,* $3 million).[10] Suppliers may be grouped in multiple sectors in accordance with the goods or services they supplied, and the retrospective premium would be the sum of the risk premium for each sector. As in Alternative 1, the ''risk'' that is the subject of this risk-informed assessment formula, and the basis for the risk premium payment, is the risk that a nuclear supplier's goods or services would provide the basis for a claim for damage resulting from a nuclear incident at a covered installation that would give rise to a call for funds under the Convention.

Section 951.8—Allocated Risk by Sector and Section 951.9—Allocated Cost by Sector

Each nuclear sector has an allocated risk based upon the relative risk that the goods or services supplied within that sector would contribute to a nuclear incident that could result in a call for funds. Each nuclear sector also would have an allocated cost, which is the product of the allocated risk of the sector multiplied by the contingent cost. For example, the facility sector has an allocated risk of 50 percent, meaning that that sector has been determined to be likely to contribute 50 percent, or half, of the risk of a nuclear incident at a covered installation giving rise to a call for funds under the Convention. If the contingent cost is $150 million, the allocated cost to the facility sector is $75 million. The same logic follows with the other sectors: The equipment and technology sector has an allocated risk of 25 percent; the nuclear materials and nuclear material transportation sector has an allocated risk of 15 percent; and the services sector has an allocated risk of 10 percent. The Department derived the allocated risk amounts based on its knowledge of the history and experience in the nuclear industry and the likelihood of the goods and services within a nuclear sector contributing to a nuclear incident of the kind for which the United States government would be required to make a payment under the Convention. In the NOI, commenters were reluctant to attribute a specified amount of risk to any given nuclear supplier sector or good or service. Because quantifiable risk amounts are essential for the risk-assessment formula, however, the Department has proposed amounts it believes appropriate and reasonable. Commenters are encouraged to propose alternative amounts and provide any and all supporting information and data for those amounts for consideration by the Department. Further, section 934(e)(2)(C)(i) requires DOE to determine the risk-based formula, by rule, every 5 years after it is originally established by regulation. Therefore, the Department notes that if this risk allocation becomes inequitably weighted because of the passage of time and other circumstances, the risk allocation for each nuclear sector would be revised as appropriate to match the relative risks among the nuclear sectors at that time.

[10] The numbers provided in the text and as parentheticals are examples only, and not intended to represent an actual case. The following hypothetical amounts illustrate how the formula would work, where it is assumed that: Contingent cost = $150 million; nuclear supplier's covered transactions = 1 nuclear reactor; allocated risk for facility sector = 50%; and aggregate risk exposure of the facility sector = 50.

Retrospective Premium Payment = risk share [.04] × allocated cost facility sector [$75,000,000] = $3,000,000

Risk share = risk exposure of nuclear supplier [2]/ aggregate risk exposure of facility sector [50] = .04 or 4%

Allocated cost facility sector = allocated risk by sector [50%] × contingent cost [$150,000,000] = $75,000,000

Risk exposure of nuclear supplier = quantity of all covered transaction of nuclear supplier [1] × 2 = 2.

Section 951.7—Risk Share by Sector and Section 951.10–951.14—Risk Exposure by Sectors

The risk share of a nuclear supplier is expressed in terms of its relative risk exposure within a sector. A nuclear supplier's risk exposure is a function of the nuclear supplier's proportional share of the aggregate risk exposure of all nuclear suppliers within the sector, weighted as a 2 or 1 in accordance with the risk associated with the good or service supplied. Each nuclear sector has its own risk exposure calculation. The aggregate risk exposure by sector is the sum of the risk exposure of all nuclear suppliers within that sector.

The risk exposure of a nuclear supplier to the facility sector is derived by first determining the quantity of all covered transactions by the nuclear supplier of a nuclear plant or a facility for the reprocessing of irradiated nuclear fuel, multiplying that number by 2, and second determining the quantity of all covered transactions of the supplier of facilities or plants for the processing of nuclear material (except facility for reprocessing irradiated nuclear fuel), or facilities where nuclear material is stored, multiplying that number by 1. The products of these two determinations are added together, and the resulting sum is then used to calculate the risk exposure of the nuclear supplier within the facility sector by comparing that number to the aggregate risk exposure of all nuclear suppliers (derived in the same manner as the risk exposure of a single nuclear supplier) in that sector. A very similar calculation is used to derive the risk exposure in the other three sectors. In each sector, a weighting of 2 is allocated to the facilities, equipment, technology, nuclear material storage facilities, nuclear material transportation and services that are associated with nuclear installations that are either a nuclear plant or a facility for the reprocessing of irradiated nuclear fuel. This weighting reflects the Department's judgment, based on its experience and expertise that those types of nuclear installations have a higher probability of experiencing a nuclear incident resulting in a call for funds under the Convention than other nuclear installations, and thus the nuclear goods or services supplied to them have a higher probability of contributing to such an incident. A weighting of 1 is allocated to the facilities, equipment, technology, nuclear material storage facilities, nuclear material transportation and services that are associated with nuclear installations that are a nuclear material processing facility, a nuclear material storage facility, or associated with nuclear material transportation. This weighting reflects the Department's judgment, based on its experience and expertise, that those types of nuclear installations have a lower probability of experiencing a nuclear incident resulting in a call for funds under the Convention than other nuclear installations, and thus the nuclear goods or services supplied to them have a lower probability of contributing to such a nuclear incident.

The main difference in the calculation of the risk exposure between the sectors is the way covered transactions are accounted for: The facility sector and the nuclear materials and nuclear transportation sector calculate risk exposure as a function of the quantity of the goods supplied in a covered transaction; the equipment and technology and services sectors calculate exposure as a function of the adjusted value of the goods or services supplied in a covered transaction. The Department proposes this distinction as a better means of calculating the relative share of a supplier's exposure within each sector. In the former two sectors, the quantity of nuclear installations supplied and the quantity of nuclear material supplied or transported better represent the market share and associated risk exposure of that nuclear supplier than the value of the good or service provided. For example, a nuclear supplier that supplied 10 nuclear reactors versus a nuclear supplier of 5 nuclear reactors would be expected, generally speaking, to have doubled the risk exposure of contributing to a nuclear incident regardless of the value of the nuclear reactors supplied. On the other hand, for the latter two sectors, the adjusted value of a supplier's covered transactions would be a better representation of its market share and associated risk exposure than the quantity supplied. For example, a nuclear supplier of equipment and technology may supply an item in a large quantity but of small value and vice versa. In such cases, the supplier's proportionate share of the market in that sector and associated risk is better represented by the value of its covered transactions than the quantity. This is particularly true of nuclear services, which is not a discrete item that can be quantified as such.

Some commenters on the NOI noted the complexity of identifying an appropriate metric to use in apportioning the contingent cost among nuclear suppliers either individually or as a group. Nevertheless, one way identified by commenters is to use the value or revenue from a nuclear supplier's covered transactions; this is the approach proposed in Alternative 1. Alternative 2 identifies the two ways discussed in the preceding paragraphs, recognizing the differences in the nature of the transactions by nuclear suppliers in the different sectors. The Department believes the approaches in Alternative 1 and 2 have merit, and requests comment on the metrics presented for both of these alternatives.

Section 951.15—Small Nuclear Supplier Exclusion

The exclusion for small nuclear suppliers is in concept the same in Alternative 2 as in Alternative 1, with some differences resulting from approaches taken in the alternatives (*i.e.,* goods and services in Alternative 1 and nuclear sectors in Alternative 2). The first difference lies in the method of assessing the risk exposure of a nuclear supplier that forms the basis for the exclusion. In Alternative 2, a small nuclear supplier may be excluded based on a risk exposure of less than a dollar amount, *e.g.,* $1,000,000, for nuclear suppliers in the equipment and technology sector and the services sector, or a risk exposure less than a quantity amount, *e.g.,* 1,000 MT of nuclear material, for nuclear suppliers in the nuclear materials and nuclear materials transportation sector. This is consistent with the method for calculating risk exposure under Alternative 2. As in Alternative 1, the Department is open to comment on what dollar amounts or quantity amounts are an appropriate basis for exclusion, as well as whether exclusion on the basis of being defined as a small business under SBA size standards is appropriate.

The second difference pertains to nuclear suppliers in the facility sector: The Department is not proposing a small nuclear supplier exception for nuclear suppliers in the facility sector. Given the composition of nuclear suppliers in that sector, the Department does not believe there are any nuclear suppliers—even suppliers of only one nuclear installation—that warrant treatment as a small nuclear supplier. The Department seeks comment on this aspect of its proposed rule for small nuclear supplier exception.

Subpart C—Payments to the United States

General Rule—Section 951.11 (Alternative 1)–951.17 (Alternative 2)

The requirements of subpart C are prescribed in section 934(h)(1) of the Act. This section states the general rule

that nuclear suppliers are required to pay the entire risk premium within 60 days of receipt of notification from the Department that payment is due, unless they elect to prorate their payment in 5 equal annual payments. The payment is to be made to the general fund of the U.S. Treasury. The amount is calculated in accordance with the formula in subpart B.

In the event amounts provided by the nuclear suppliers are insufficient to cover the United States' full contribution at the time it is due, for example, if suppliers elect to prorate their payments over 5 years in accordance with section 934(h)(1)(B)(ii), the United States may be required to seek an appropriation in order to meet its full contribution requirement. In the event such an appropriation is enacted, as in the example noted in the preceding sentence, the funds appropriated would be used to pay United States' government obligations and would be reimbursed by nuclear suppliers' prorated payments per section 934(h)(1)(B)(ii). The Department seeks comment on several facets of a nuclear supplier's obligation and options to fulfill the risk premium payment requirement. For example, the Department is interested in comments on the proposed payment plans and any alternative options for payment plans that meet the United States government's obligations under the CSC and are consistent with section 934. In addition, the Department seeks comment on whether nuclear suppliers should be required to demonstrate that they have an adequate financial mechanism (such as a state-administered fund, bond, private insurance, or certificate of deposit) to ensure the availability of financial resources sufficient to cover the risk premium payment to ensure full and timely payment to the United States government. DOE is also seeking comment on the feasibility, cost and necessity of demonstrating the adequate availability of funds, and whether such a financial demonstration, if appropriate, should be a mandatory or discretionary requirement for suppliers.

Annual Payments—Section 951.12 (Alternative 1)–Section 951.18 (Alternative 2)

This section implements section 934(h)(1)(B)(ii) of the Act, which permits a nuclear supplier to prorate their payment into 5 equal payments due annually. The 5 annual payments must include interest on the unpaid balance at the prime rate prevailing at the time the first payment is due.

Vouchers—Section 951.13 (Alternative 1)–Section 951.19 (Alternative 2)

This section implements section 934(h)(1)(C) of the Act, which requires a nuclear supplier to submit payment certification vouchers to the Secretary of Treasury in accordance with 31 U.S.C. 3325. To fulfill the requirement of section 934, nuclear suppliers would submit a voucher to the Secretary of Treasury consistent with 31 U.S.C. 3325 in regard to: Proper form; certified and approved; and computed correctly based on the facts. Nuclear suppliers would submit the voucher to the Secretary of Treasury concurrent with the payment to the general fund. The voucher would be in the form of a letter signed by an official with authority to bind the company that certifies the payment made to the general fund of the Treasury is made pursuant to the Department's notification under section 951.4, the amount is computed correctly, and the specifics of the payment plan, *e.g.,* the amount paid, the date of payment, and details of the payment plan: One-time, or in 5 equal amounts annually.

Failure to Pay—Section 951.14 (Alternative 1)–Section 951.20 (Alternative 2)

As permitted under section 934(h)(3), the Department may penalize a nuclear supplier for failure to pay the required risk premium. This section of the proposed rule states that the Department shall recover from a nuclear supplier that does not pay the risk premium no later than 60 days after receipt of a notification: (1) The amount of the payment due; (2) any applicable interest on the payment at the prime rate prevailing at the time the first payment is due; and (3) a penalty of not more than twice the amount of the payment due from the nuclear supplier.

The Department has made the penalty payment mandatory in the proposed rule. Payment by nuclear suppliers on a timely basis is critical to the proper functioning of the regulation and the ability of the United States to timely meet its international commitments. The penalty provisions of section 934(h)(3) indicate Congressional intent to hold nuclear suppliers to their obligation to fully fund payments due from the United States under the CSC, with interest added to late payments and a penalty imposed—in addition to the premium payment—of up to double the amount of the premium payment due for suppliers that fail to pay on time and in the amounts required. Accordingly, the Department proposes the penalties for failure to pay the risk premiums on time and in full be mandatory, strictly enforced, and assessed in full, except in the case of extraordinary circumstances. The Department seeks comment on whether the penalty payment due should be discretionary, and what factors may be appropriate and considered by the Department to mitigate the penalties or support a claim of extraordinary circumstances in the case of a delinquent supplier.

Subpart D—Information Collection

Reporting Requirements for Prior Transactions—Section 951.15 (Alternative 1)–Section 951.21 (Alternative 2)—Reporting Requirements for Prior Transactions

Section 934(f) of the Act permits the Department to collect information from nuclear suppliers as necessary to develop and implement the formula for calculating the risk premium payments. This section requires a report, within 6 months of the effective date of the regulation, from nuclear suppliers regarding each reportable transaction they have had prior to the effective date of any final regulations. The report must be certified and signed by an official with authority to bind the company. The information necessary for the Department to calculate the risk premium includes: The date and description of each reportable transaction; the location of the nuclear installations involved in each transaction; identification of the volume or quantity of each item involved in a reportable transaction; the value of each identified item, and the total value for each reportable transaction.

Importantly, the information to be reported pertains only to ''reportable transactions'' as defined in the proposed rule, and therefore not all transactions and not all nuclear suppliers are subject to the reporting requirements. As previously described, a reportable transaction is a transaction by a covered nuclear supplier that: (1) Occurred after a certain date as specified in Alternative 1 or 2; and (2) involves only those items or nuclear sectors identified in the proposed rule. The transaction must also involve nuclear goods or services supplied to a foreign nuclear installation or transportation outside the United States of nuclear material to or from a nuclear installation.

The Department received several comments about reporting requirements under the rule. Most commenters believed the existing reporting on nuclear exports was inadequate to provide the information required for implementation of section 934, and that

additional reporting by nuclear supplier would be necessary although not desirable. The Department is aware that existing reporting mechanisms may not be sufficient to meet its needs and therefore proposes in this rule to require the necessary information be provided by nuclear suppliers. DOE notes, however, that many of the qualifications in the rule regarding who needs to report and what transactions need to be reported operate to, among other things, minimize the impact of reporting requirements on nuclear suppliers. Not all transactions of all nuclear suppliers are required to be reported. The Department believes that the rule is structured such that the reporting requirements for nuclear suppliers are circumscribed and manageable, and would not cause undue burden on the nuclear industry. The Department seeks comment from the public on several aspects of its reporting requirements: Whether the 6 month period for reporting on prior transactions is adequate; the number of nuclear suppliers affected by the reporting requirements; the impact of the requirements on those nuclear suppliers in terms of burden hours, capital/start-up costs and competitiveness; and suggestions for alternative methods or criteria to streamline the reporting requirements while achieving the objectives of the law.

Annual Reporting Requirements—Section 951.16 (Alternative 1)–Section 951.23 (Alternative 2)

In addition to a one-time report on prior transactions, this section institutes an annual reporting requirement due by March 15th of each year for transactions in the prior year. The same information required for prior transactions would be required on an annual basis. The annual reporting requirement enables the Department to maintain and compile records on reportable transactions that can be readily accessed in the event there is a nuclear incident and a call for funds under the Convention.

Disclosure Requirements—Section 951.17 (Alternative 1)–Section 951.23 (Alternative 2)

This section provides the disclosure requirements for information provided to the Department under the reporting requirements of this subpart. Information reported to the Department may be subject to public disclosure unless the information is protected from disclosure under the Freedom of Information Act and DOE implementing regulations. While the Department does not believe the reporting requirements involve information that would be trade secrets or other proprietary information, the proposed rule provides protection from disclosure for such information that is appropriately marked and upon a satisfactory showing to the Department that the information should not be disclosed under applicable law.

Appendices

The appendices to Alternative 1 of the proposed rule contain the lists of nuclear goods and services that form the basis for determining the risk premium payment, and are subject to reporting by nuclear suppliers as reportable transactions. The Department reviewed available and relevant data and information on nuclear goods and services, in particular those nuclear goods and services that are important to safety, to determine the risk or the likelihood that each such good or service would contribute to legal liability for a nuclear incident that would require a call for funds under the Convention.

The items in the appendices were derived from information and data in NRC regulations and associated guidance, the Commerce Control List (CCL), and relevant international guidance documents. The NRC regulations and guidance relied upon include: Regulatory Guide 1.26, ''Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,'' Revision 4 (March 2007); NUREG 0800 Standard Review Plan, Revision 2 (March 2007) (*e.g.,* section 3.2.2); 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' (*e.g.,* subsection 50.2, 50.55a, and Appendices A and B); 10 CFR part 21; and 10 CFR part 110, ''Export and Import of Nuclear Equipment and Material (*e.g.,* Appendix A). In particular, appendix A to 10 CFR part 110, which provides an illustrative list of nuclear reactor equipment for export licensing authority, was a useful reference point for compiling the list of primary nuclear items for appendix A to the proposed rule. Several of the items in appendix A to this rule, and 10 CFR part 110, appendix A, also appear in the CCL, 15 CFR 774.2, Supplement 1, ''Category 0—Nuclear Materials, Facilities and Equipment'', although export of these items is subject to regulation by NRC, not Commerce. Several commenters recommended 10 CFR part 110 to the Department for consideration of nuclear items that could reasonably be assigned the highest level of responsibility and liability for contingent costs.

In addition, items on the list were derived from relevant international references, such as the IAEA Information Circulars INFCIRC/254/Part 1 as revised and INFCIRC/209 as revised. The IAEA Information Circulars are the Nuclear Suppliers Group and Zangger Committee Guidelines and technical annexes. These technical annexes comprise the list of nuclear materials, equipment, facilities, and technologies that are controlled by the members of the Nuclear Suppliers Group and Zangger Committee. The United States is a founding member of both export control regimes and the lists are the basis of the DOE's and NRC's export control regulations.

The following provides a description of each appendix and the items contained therein. The Department welcomes comments and suggestions from the nuclear industry on other sources not addressed here that are relevant and supportive of the items listed in the appendices.

Appendix A—List of Primary Nuclear Items

This list contains items the Department deemed most likely to contribute to a nuclear incident that would result in a call for funds, taking into account the risk factors identified in section 934 and other relevant data and information. The list includes safety-related systems, structures and components subject to QA requirements (Quality groups A, B and C), and that are relied upon to mitigate the consequences of nuclear plant events or accidents.

Appendix B—List of Secondary Nuclear Items

This list contains the items the Department deemed secondarily likely to contribute to a nuclear incident that would result in a call for funds, taking into account the risk factors identified in section 934 and other relevant data and information. The items listed include systems, structures and components of a nuclear installation that are subject to QA requirements and perform a nuclear function albeit not a direct safety function, for example, waste processing or fuel handling. The list of items does not include balance-of-plant equipment; [11] however, as such

[11] Balance-of-plant equipment generally refers to plant structures, systems and components used to generate electricity but not part of the nuclear and safety systems. Such systems are typically comprised of the turbine-generator and associated control lubricating oil and cooling systems; main condenser, condensate and condensate polishing; condenser cooling water, steam and feedwater; auxiliary boilers ventilation; fire protection and

Continued

items perform no nuclear or safety-related function.

III. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

National Export Initiative. The Department seeks additional commentary and specific information from the nuclear industry on the potential impacts to U.S. competitiveness in the nuclear export arena and the President's National Export Initiative. The Department is also interested in receiving comment on which alternative regulation, the first or the second, is better suited to mitigate the impacts, if any, on United States' competitiveness in the nuclear export arena.

Covered nuclear supplier. The Department seeks comment on whether NRC's part 21 regulations, or some other regulatory requirement or concept such as the quality assurance requirements in 10 CFR part 50, Appendix B, are appropriate criteria to determine which nuclear suppliers should be defined as a covered nuclear supplier.

List of covered installations. The Department seeks additional commentary from the public on the suggestion that it produce a list of the nuclear installations outside the United States that would be covered installations under the Convention.

Alternative 1—risk ranking in appendices. The appendices in the proposed rule identify particular nuclear goods and services to which they assign a risk rating or ranking-primary or secondary- and a corresponding weight—2 or 1. The Department seeks comment from the public on the risk sharing classification of covered items in the appendices and suggestions, with supporting bases, for additions or deletions from the list.

Alternative 1—small nuclear supplier exclusion. The Department seeks comment on what dollar amount or other criterion, such as classification as a ''small business'' under SBA size standards, is reasonable to use for exclusion of small nuclear suppliers.

Alternative 2—small nuclear supplier exclusion. The Department seeks comment from the public on what dollar or quantity amounts are an appropriate basis for exclusion, as well as whether exclusion on the basis of being defined as a ''small business'' under SBA size standards is appropriate. The Department also seeks comment on whether there are any nuclear suppliers in the facility sector that would or should qualify for the small nuclear supplier exception.

Retrospective premium payment cap. The Department proposes a cap on the retrospective premium payment for any one nuclear supplier. The Department seeks comment from the public on a specific amount, such as $25 million, or percentage of contingent cost, such as 5% or 25%, that is appropriate as a cap on any one supplier's premium payment. The Department welcomes additional comment and feedback from the public on the process for ensuring the United States' is paid in full by nuclear suppliers for its contributions under the Convention.

Alternative 2—nuclear supplier sectors. The nuclear supplier sectors proposed in the rule are: (1) Facility; (2) equipment and technology; (3) nuclear material and nuclear material transportation; and (4) services. The Department seeks comment on other ways to define nuclear sectors (*e.g.,* defining the sectors based upon the stages of the fuel cycle or by installation type).

Alternative 2—lead nuclear supplier. The Department seeks comment on the descriptor of a lead nuclear supplier appropriate for inclusion in the rule to further clarify the definition of facility sector nuclear suppliers.

Alternative 2—nuclear sectors. The Department seeks comment from the nuclear industry on whether the nuclear sector approach is appropriately structured, should be defined in the rule, and alternative suggestions.

Alternative 2—allocated risk by sector. Each nuclear sector has an allocated risk based upon the relative risk that the goods or services supplied within that sector would contribute to a nuclear incident that could result in a call for funds. The Department encourages commenters to propose alternative risk allocation amounts per sector, accompanied by any and all supporting information and data for those amounts.

Risk share calculation. The Department seeks comment on the metrics proposed in Alternatives 1 and 2 associated with the calculation of a supplier's risk share.

Payments to the United States. The Department seeks comments from the public on the proposed payment plans whereby, in accordance with section 934(h)(1)(B)(i) and (ii), nuclear suppliers must pay the required deferred payment to the general fund of the Treasury within 60 days after notification by the Secretary, or elect to prorate payment in 5 equal annual payments (including interest on the unpaid balance at the prime rate prevailing at the time the first payment is due). The Department seeks comment on the proposed payment plans and any alternative options for payment plans that meet the United States government's obligations under the CSC and are consistent with section 934. The Department is also seeking comment on whether nuclear suppliers should be required to demonstrate that they have an adequate financial mechanism (such as a state-administered fund, bond, private insurance, or certificate of deposit) to ensure the availability of financial resources sufficient to cover the risk premium payment to ensure full and timely payment to the United States government. Comments may address the feasibility, cost and necessity of demonstrating the adequate availability of funds, and whether such a financial demonstration, if appropriate, should be a mandatory or discretionary requirement for suppliers.

Failure to pay. The Department has proposed a mandatory penalty payment. The Department seeks comment on whether the penalty payment should be discretionary, and what factors may be appropriate and considered by the Department to mitigate the penalties or support a claim of extraordinary circumstances in the case of a delinquent supplier.

Appendices. The Department welcomes comments and suggestions from the nuclear industry on other sources not addressed here that are relevant and supportive of the items listed in the appendices.

Reporting requirements. The Department seeks comment from the public on several aspects of its reporting requirements: Whether the 6 month period for reporting on prior transactions is adequate; the number of nuclear suppliers affected by the reporting requirements; the impact of the requirements on those nuclear suppliers in terms of burden hours, capital/start-up costs, and competitiveness; and suggestions for alternative methods or criteria to streamline the reporting requirements while achieving the objectives of the law. In addition, the Department requests comment on the probability of a nuclear supplier having records of transactions dating back to 1960, the feasibility of supplier's meeting the reporting requirements for those transactions, and appropriate mechanisms for DOE to determine the

associated electrical, instrumentation and control systems; electrical transformers; and building structures.

information submitted is complete and accurate.

Impact on small entities. DOE has proposed two alternative-risk-assessment methods and requests comment on whether either alternative would result in a lower impact on small entities. The Department requests comment from the public on any other alternatives that could minimize impacts on small entities.

Collection of information. The Department seeks comment on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of information to be collected; (d) ways to minimize the burden of the collection of information, including the use of automated collection techniques or other forms of technology; and (e) ways to determine the information collected is complete and accurate.

IV. Public Participation

A. Information Session

DOE will hold an information session open to the public on January 7, 2015, from 10:00 a.m. to 12:00 noon in Washington, DC. The information session will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585–0121. To attend, please notify Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.*

The session will be conducted by DOE to provide interested parties with an overview and description of the proposed rulemaking to facilitate review and comment by the public. Members of the public are welcome to attend the meeting, and, if time allows, a question and answer may be held. DOE does not expect participants to be prepared to offer substantive comments on the proposed rulemaking before or at the information session. DOE plans to hold public workshop(s) on the proposed rulemaking at a later date within the comment period that will provide the public with an expanded opportunity to comment orally and in writing on the proposed rulemaking. The date, time and place of such workshops will be announced in subsequent **Federal Register** notice(s).

B. Attendance at the Information Session

The information session will be conducted in an informal style by DOE. There shall be no discussion of proprietary information, costs or prices, market shares, or other commercial matters. A court reporter will record the proceedings of the public meeting, and a transcript will be posted on the DOE Web site at *http://www.energy.gov/gc/convention-supplementary-compensation-rulemaking.*

Please note that foreign nationals participating in the information session are subject to advance security screening procedures which require advance notice prior to attendance at the information session. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Brenda Edwards at (202) 586–2945 or by email to *Brenda.Edwards@ee.doe.gov* so that the necessary procedures can be completed.

DOE requires visitors with laptop computers to be checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building will be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the Visitors' Desk to have devices checked before proceeding through security.

Due to the REAL ID Act, implemented by the Department of Homeland Security (DHS), there have been recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. Territories. Drivers' licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required. DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, American Samoa, Arizona, Louisiana, Maine, Massachusetts, Minnesota, New York, Oklahoma, and Washington. Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; and Enhanced Driver's License or Enhanced ID-Card issued by the states of Minnesota, New York, or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License) or military ID or other Federal government issued Photo-ID card.

V. Regulatory Review Requirements

A. Review Under Executive Order 12866

The Department has determined that this regulatory action is an ''economically significant action'' under Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended by Executive Order 13258 (67 FR 9385, February 26, 2002). Accordingly, the Department submitted this NOPR to the Office of Information and Regulatory Affairs in the Office of Management and Budget, which has completed its review under E.O. 12866.

This discussion assesses the potential costs and benefits of this notice of proposed rulemaking. This regulation affects United States nuclear suppliers that meet the requirements for contribution to the retrospective risk pooling program established by the proposed regulation. U.S. nuclear suppliers that qualify for participation in the retrospective risk pooling program would be assessed a pro-rata share of the contingent cost the United States government is required to contribute to the international supplementary fund under the Convention in the event of a covered nuclear incident. The United States government's cost (to be funded by U.S. nuclear suppliers) would be determined pursuant to the rules of the Convention and, though the amount is dependent on external factors such as the nuclear rated capacity of a CSC member state, could be in the range of $150 million. Any single U.S. nuclear supplier's cost, referred to as the retrospective premium payment, is dependent upon application of the risk-informed assessment formula. DOE proposes two alternative formulas for calculating the retrospective premium payment. Under either formula, a U.S. nuclear supplier's premium payment is a function of the risk share of the nuclear supplier relative to other nuclear suppliers; a nuclear supplier's risk share (*e.g.,* 2%) is multiplied by the contingent cost (*e.g.,* $150 million) to derive the premium payment owed by the nuclear supplier (*e.g.,* $3 million). While the exact number of U.S. nuclear suppliers potentially affected by this rule and the amount they would owe is not specifically known, the proposed rule is structured to exclude certain nuclear suppliers (*e.g.,* small nuclear suppliers), and impose a cap on costs to any one nuclear supplier (*e.g.,* $25 million). These and other measures in the proposed rule are intended to limit the population of nuclear suppliers affected by the rule to those suppliers most likely to be exposed to claims for

damage resulting from a nuclear incident and therefore are most likely to benefit from the rule.

The benefits of the proposed rule to a U.S. nuclear supplier far outweigh the costs of the rule. Outside of the Convention, U.S. nuclear suppliers are not covered by a global nuclear liability regime that provides consistent rules for dealing with legal liability. U.S. nuclear suppliers are faced with a multitude of legal regimes in a variety of foreign countries to which they supply nuclear goods or services, creating potential legal liabilities in uncertain forums and in amounts that could reach many millions or tens of millions and well above the costs contemplated in the proposed rule. As a CSC member state, the United States and its nuclear suppliers benefit from the principles of nuclear liability law followed by all CSC member states, such as channeling legal claims to the nuclear operator and limiting litigation to the courts in the member state where the nuclear incident occurred. These principles not only operate to provide prompt and equitable compensation to victims of a nuclear incident, they provide stability and, in effect, insurance to U.S. nuclear suppliers when engaging in commercial transactions with nuclear installations abroad. The potential cost to a nuclear supplier is relatively small by comparison to these benefits. Indeed, the potential cost to a nuclear supplier may never even accrue and would be zero, as the premium payment is deferred and not owed unless and until a covered incident occurs, while the benefits of the Convention would accrue as soon as it goes into effect and are not dependent on payment of the premium.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires that an agency prepare an initial regulatory flexibility analysis for any regulation for which a general notice of proposed rulemaking is required, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)). As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of General Counsel's Web site (*http://energy.gov/gc/guidance-opinions-0*). DOE reviewed the proposed rule under the provisions of the RFA and the procedures and policies published on February 19, 2003.

As a result of this review, DOE has prepared an IRFA for small nuclear suppliers, a copy of which DOE will transmit to the Chief Counsel for Advocacy for the Small Business Administration (SBA) for review under 5 U.S.C. 605(b). As presented and discussed below, the IFRA describes potential impacts on small nuclear suppliers and discusses alternatives that could minimize these impacts. A statement of the reasons, objectives and legal basis for the proposed rule is set forth elsewhere in the preamble and is not detailed here. The other requirements of section 5 U.S.C. 603(b) are addressed below.

1. Description and Estimated Number of Small Entities Regulated

DOE used the SBA's small business size standards to determine whether any small entities may be subject to the requirements of the rule. See 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.* Given the variety and differences in goods and services that U.S. nuclear suppliers may supply to foreign nuclear installations, DOE estimates that U.S. nuclear suppliers may fit within one or more sectors and codes listed in the NAICS, including but not limited to: 1) manufacturing sector, NAICS 238990, ''All Other Specialty Trade Contractors'' (size limit of $14 million), NAICS 332996, ''Fabricated Pipe and Pipe Fitting Manufacturing'' (size limit 500 employees), NAICS 332999 ''All Other Miscellaneous Fabricated Metal Product Manufacturing'' (size limit 500 employees), NAICS 336999, ''All Other Transportation Equipment Manufacturing'' (size limit 500 employees), and NAICS 33999, ''All Other Miscellaneous Manufacturing'' (size limit 500 employees); retail trade sector, NAICS 454319, ''Other Fuel Dealers'' (size limit $7 million); and professional, scientific and technical services sector, NAICS 541690 ''Other Scientific and Technical Consulting Services'' (size limit $7 million).

Given the variety and differences among goods and services provided by U.S. nuclear suppliers, and the possibility that some nuclear suppliers would not fall within the exclusions in the proposed rule for small nuclear suppliers, DOE assumes that some nuclear suppliers may meet the SBA's definition of a small business whose goods or services may be covered by this rulemaking. DOE notes that it is considering exclusion of small nuclear suppliers that meet the SBA size standard for a small business. Under this approach, small businesses would not be impacted by the rule.

2. Description and Estimate of Compliance Requirements

The proposed rulemaking requires a nuclear supplier subject to the retrospective risk pooling program make one initial and thereafter annual reports to the Department regarding its reportable transactions of exported nuclear goods or services to foreign installations. In the event of a nuclear incident at a covered nuclear installation, nuclear suppliers would be required to make a retrospective premium payment to provide funds totaling in the aggregate the amount of the United States government's contribution under the Convention. The retrospective premium payment would entail the primary costs to a small nuclear supplier under the rule (assuming for analysis purposes they are a small nuclear supplier that has not been excluded from operation of the rule); it is not expected that reporting costs would be substantial for a small business. These compliance requirements do not require any capital investments, improvements, or other production costs or changes to small business operations.

The cost of compliance, or the premium payment, owed by a nuclear supplier is prorated based on its risk exposure and risk share relative to other nuclear suppliers. Because risk exposure and risk share are a function of the value and/or volume of goods or services exported by a nuclear supplier, as calculated under either Alternative 1 or 2 in the preamble discussion of Subpart B above, it is expected that a small nuclear supplier's prorated share of the total contingent cost—estimated to be at most approximately $150 million—would be small relative to other nuclear suppliers with more significant transactions in value or quantity. In any event, the amount owed by any one nuclear supplier would be limited, as the proposed rule also includes a proposed cap on premium payments. This proposed rule suggests a cap of $5 million or some other amount or percentage of the total contingent cost, with a request for comment and alternative suggestions on the amount of this cap. The combination of these factors ensures that small businesses would be minimally impacted by the

proposed rule and the cost of compliance, consistent with the requirements of section 934.

3. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being considered today.

4. Significant Alternatives to the Proposed Rule

As discussed in this section and elsewhere in this proposed rulemaking, DOE is required under section 934 of the Act to promulgate a rule establishing a retrospective risk pooling program for U.S. nuclear suppliers that obligates such suppliers to provide funds in the same amount as the United States government's contingent costs for contributions under to the supplementary fund the Convention. DOE has proposed two alternative risk-assessment methods and seeks comment on whether either of those alternatives would result in a lower impact on small entities. This proposed rule also includes mitigating and potentially exclusionary factors specifically for small businesses. This proposed rule would exclude small nuclear suppliers, which can be defined in various ways including that a nuclear supplier qualifies as a small business under the SBA regulations. This proposed rule also operates in such a manner that, if it applies, a nuclear supplier's premium payment is prorated based upon their risk share and exposure, measured in terms of value or quantity of goods sold, relative to other nuclear suppliers. Further, this proposed rule includes a cap on premium payments by any one nuclear supplier. DOE believes that this proposed rule has been structured to minimize its applicability to small businesses and, where it applies, to minimize the costs to any small nuclear supplier. DOE seeks comment on any other alternatives that could minimize the impacts on small businesses.

C. Review Under the Paperwork Reduction Act

Section 951, subpart D, contains information collection requirements pertaining to a nuclear supplier's reportable transactions, as defined in the proposed rule, involving exports of nuclear goods or services. This information collection is authorized under section 934(f), which permits the Secretary to collect information from nuclear suppliers as necessary to develop and implement the formula for calculating the deferred payment under the retrospective risk pooling program, and requires nuclear suppliers to make available such information, reports, records, documents and other data as the Secretary determines necessary and appropriate to develop and implement the formula. This proposed rule requires a one-time report, within 6 months of the effective date of the rule, and annually thereafter, from nuclear suppliers regarding each reportable transaction they have had either since 1960 or 2007, depending upon the type of transaction. The information to be collected pertains to a nuclear supplier's export transactions involving nuclear goods or services, including information on: description of the transaction; date of the transaction; location of the nuclear installation to which the exported item was provided; quantity of the exported item(s); and value of the exported item(s).

These provisions will not become effective until the Office of Management and Budget (OMB) has approved them pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 1320.1 *et seq.*

The Department has submitted to OMB for clearance the collection of information in subsection D, under the provisions of the Paperwork Reduction Act of 1995. This information collection request contains: (1) OMB Number: New; (2) Information Collection Request Title: Convention on Supplementary Compensation for Nuclear Damage Contingent Cost Allocation; (3) Type of Request: New; (4) Purpose: The information to be collected is critical to implementation of the risk-assessment formula and calculation of the retrospective risk premium due by a nuclear supplier under the retrospective risk pooling program, and will require the collection and submission of information on reportable transactions by nuclear suppliers covered under the retrospective risk pooling program; (5) Annual estimated number of Respondents: 25; (6) Annual Estimated Number of Total Responses: 25; (7) Annual Estimated Number of Burden Hours: 25 hours annually, and a one-time reporting requirement totaling 100 hours; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $8,000 annually, and a one-time reporting requirement cost of $32,000.

The Department invites public comment on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the number of estimated respondents and the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments may be sent to Sophia Angelini (see **ADDRESSES**) and by email to *OIRA_Submission@omb.eop.gov.*

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act

DOE has reviewed these proposed regulations pursuant to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality's regulations (40 CFR parts 1500–08), and DOE's implementing regulations (10 CFR part 1021). Categorical Exclusion A6 (in Appendix A to Subpart D of 10 CFR part 1021) applies to rulemakings that are strictly procedural, and thus applies to this rulemaking. DOE has determined that there are no extraordinary circumstances related to this proposal that may affect the significance of the environmental effects of the proposal. Accordingly, DOE has determined that this action is categorically excluded from the need to prepare an environmental impact statement or an environmental assessment pursuant to NEPA.

E. Review Under Executive Order 13132

Executive Order 13132 ''Federalism,'' 64 FR 43255 (August 10, 1999), requires agencies to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have ''federalism implications.'' Policies that have federalism implications are defined in the Executive Order to include regulations that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

This regulatory action has been determined not to be a ''policy that has federalism implications;'' that is, it does not have substantial direct effects on the

States, on the relationship between the national government and the States, nor on the distribution of power and responsibilities among various levels of government under Executive Order 13132, 64 FR 43255 (August 10, 1999).

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4779, February 7, 1996) imposes on Federal agencies the general duty to adhere to the following requirements: eliminate drafting errors and needless ambiguity, write regulations to minimize litigation, provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Section 3(b) requires Federal agencies to make every reasonable effort to ensure that a regulation, among other things: clearly specifies the preemptive effect, if any, adequately defines key terms, and addresses other important issues affecting the clarity and general draftsmanship under guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive Agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department has completed the required review and determined that, to the extent permitted by law this final rule meets the relevant standards of Executive Order 12988.

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4779, February 7, 1996) imposes on Federal agencies the general duty to adhere to the following requirements: Eliminate drafting errors and needless ambiguity, write regulations to minimize litigation, provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Section 3(b) requires Federal agencies to make every reasonable effort to ensure that a regulation, among other things: clearly specifies the preemptive effect, if any, adequately defines key terms, and addresses other important issues affecting the clarity and general draftsmanship under guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department has completed the required review and determined that, to the extent permitted by law; this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, or Tribal governments and the private sector. Pub. L. 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal government, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)). The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/guidance-opinions-0*.

Although this proposed rule does not contain a Federal intergovernmental mandate, it may impose expenditures of $100 million or more on the private sector. Specifically, the final rule could impose expenditures of $100 million or more for a nuclear supplier in the event that nuclear supplier's covered transactions result in a risk premium payment owed by the supplier exceeding $100 million.

Section 202 of UMRA authorizes an agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the proposed rule. 2 U.S.C. 1532(c). The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of this proposed rule and the analysis under Executive Order 12866 respond to those requirements.

H. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Government Actions and Interference with Constitutionally Protected Property Right,'' 53 FR 8859 (March 18, 1988) that this regulation would not result in any takings which might require compensation under the Fifth Amendment to the U.S. constitution.

I. Review Under Executive Order 13211

Executive Order 13211 (''Actions Concerning Regulations That Significantly Affect Energy, Supply, Distribution, or Use''), 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy and is, therefore, not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this NOPR.

List of Subjects in 10 CFR Part 951

Nuclear energy, Nuclear power plants and reactors, Nuclear materials, Treaties.

Issued in Washington, DC, on December 10, 2014.

Steven P. Croley,

General Counsel.

For the reasons set forth in the preamble, the Department of Energy proposes to amend Chapter III of title 10 of the Code of Federal Regulations by adding a new part 951 to read as follows:

Alternative 1—Risk-Informed Assessment Formula by Nuclear Goods and Services

PART 951—CONVENTION ON SUPPLEMENTARY COMPENSATION FOR NUCLEAR DAMAGE CONTINGENT COST ALLOCATION

Subpart A—General Provisions

Subpart B—Retrospective Risk Pooling Program

Subpart C—Payments to the United States

Subpart D—Information Collection

Authority: 42 U.S.C. 2201, 42 U.S.C. 17373.

Subpart A—General Provisions

§ 951.1 Purpose.

This part establishes the regulations for the implementation of section 934 (42 U.S.C. 17373) of the Energy Independence and Security Act of 2007 (Pub. L. 110–140), which provides for the proration of a retrospective premium among nuclear suppliers for the insurance against potential liability for nuclear damage provided by the adherence of the United States to the Convention.

§ 951.2 Scope.

This part covers nuclear incidents that occur outside the United States that result in a request for funds and that are not a Price-Anderson incident.

§ 951.3 Definitions.

For purposes of this part, words shall be defined as provided for in the Atomic Energy Act and in section 934 of the Act and as follows—

Act means the Energy Independence and Security Act of 2007 (Pub. L. 110–140).

Adjusted value means the value (expressed in U.S. dollars) received by a nuclear supplier for an item, adjusted to reflect inflation from the date of the covered transaction involving the item to the date of the nuclear incident for which the retrospective premium payment of the supplier is being calculated.

Aggregate risk exposure means the sum of the risk exposures for all nuclear suppliers.

Contingent cost means the cost to the United States in the event of a covered incident the amount of which is equal to the amount of funds the United States is obligated to make available under paragraph 1(b) of Article III of the Convention.

Convention means the Convention on Supplementary Compensation for Nuclear Damage, done at Vienna on September 12, 1997.

Covered incident means a nuclear incident the occurrence of which results in a request for funds under the Convention.

Covered installation means a nuclear installation at which the occurrence of a nuclear incident could result in a request for funds under the Convention.

Covered nuclear supplier means a nuclear supplier whose goods or services, if supplied in the United States, would be subject to the requirements of 10 CFR part 21.

Covered person means—

(1) A United States person; or

(2) An individual or entity (including an agency or instrumentality of a foreign country) that is located in the United States, or carries out an activity in the United States; but

(3) Does not include the United States or any agency or instrumentality of the United States.

Covered transaction means any reportable transaction by which a nuclear supplier is the final nuclear supplier to provide any item listed in appendix A or B of this part for use in the design, construction, operation, or decommissioning of any covered installation or in the transportation of material to or from a covered installation.

Department means the United States Department of Energy.

Final nuclear supplier means the nuclear supplier that obtains, where required, an NRC general or specific license under 10 CFR part 110, Department of Commerce export license under 15 CFR part 734, or DOE authorization under 10 CFR part 810, for the export of the item(s) involved in a reportable transaction.

Nuclear installation means:

(1) Any nuclear reactor facility or plant other than one with which a means of sea or air transport is equipped for use as a source of power, whether for propulsion thereof or for any other purpose;

(2) Any facility or plant using nuclear fuel for production of nuclear material, or any facility or plant for the processing of nuclear material, including any facility or plant for the reprocessing of irradiated nuclear fuel; and

(3) Any facility or plant where nuclear material is stored, other than storage incidental to the carriage of such material; provided that the Installation State may determine that several nuclear installations of one operator which are located at the same site shall be considered a single nuclear installation.

Nuclear material means nuclear fuel, other than natural or depleted uranium, capable of producing energy by a self-sustaining chain process of nuclear fission outside a nuclear reactor, either alone or in combination with some other material, and radioactive products or waste, where radioactive products or waste means any radioactive material produced in, or any material made radioactive by exposure to the radiation incidental to the production or utilization of nuclear fuel, but does not include radioisotopes which have reached the final stage of fabrication so as to be usable for any scientific, medical, agricultural, commercial or industrial purpose.

Nuclear supplier means a covered person (or a successor in interest of a covered person) that—

(1) Supplies facilities, equipment, fuel, services, or technology pertaining to the design, construction, operation, or decommissioning of a covered installation, or

(2) Transports nuclear materials that could result in a covered incident.

Price-Anderson incident means a covered incident for which section 170 of the Atomic Energy Act of 1954 (42 U.S.C. 2210) would make funds available to compensate for public liability (as defined in section 11 of that Act (42 U.S.C. 2014)).

Reportable transaction means any transaction by a covered nuclear supplier after 1959 to provide any item listed in appendix A of this part, or after 2007 for items listed in appendix B of this part, for use in the design, construction, operation, or decommissioning of any nuclear installation outside the United States or in the transportation outside the United States of nuclear material to or from a nuclear installation.

Request for funds means a request for funds pursuant to Article VII of the Convention.

Secretary means the Secretary of Energy.

United States means, when used in a geographic sense, the same as the definition of the term in section 11 of the Atomic Energy Act of 1954 and includes the Commonwealth of Puerto Rico, any other territory or possession of the United States, and the waters of the United States territorial sea under Presidential Proclamation Number 5928, dated December 27, 1988 (43 U.S.C. 1331 note).

United States person means—

(1) Any individual who is a resident, national, or citizen of the United States (other than an individual residing outside of the United States and employed by a person who is not a United States person); and

(2) Any corporation, partnership, association, joint stock company, business trust, unincorporated organization, or sole proprietorship that is organized under the laws of the United States.

Subpart B—Retrospective Risk Pooling Program

§ 951.4 Role of the Department.

Within 60 calendar days of a request for funds, the Department shall calculate the retrospective premium payment for each nuclear supplier in accordance with the rules set forth in this subpart and notify each nuclear supplier though publication in the **Federal Register**.

§ 951.5 Retrospective premium payment.

The retrospective premium payment for a nuclear supplier shall be the product of the risk share of the nuclear supplier and the contingent cost.

§ 951.6 Risk share.

The risk share of a nuclear supplier shall be the quotient of the risk exposure of the nuclear supplier divided by the aggregate risk exposure.

§ 951.7 Risk exposure.

The risk exposure of a nuclear supplier shall be the sum of the following products:

(a) The adjusted value of all covered transactions by the nuclear supplier to the extent such transaction involve items listed in appendix A of this part multiplied by 2; and

(b) The adjusted value of all covered transactions by the nuclear supplier to the extent such transactions involve items listed in appendix B of this part multiplied by 1.

§ 951.8 Aggregate risk exposure.

The aggregate risk exposure is the sum of the risk exposure of all nuclear suppliers.

§ 951.9 Small nuclear supplier exclusion.

A nuclear supplier with a risk exposure of less than [amount, *e.g.,* $1,000,000 or some other amount, or exclusion for a nuclear supplier that qualifies as a ''small business'' under Small Business Administration codes] shall not be assessed a retrospective premium payment and shall not be included in the aggregate risk exposure and calculation of retrospective premium payments for other nuclear suppliers.

§ 951.10 Retrospective premium payment cap.

(a) The retrospective premium payment of a nuclear supplier shall not exceed [insert amount, *e.g.,* 5%, 25%, or some other percentage; or a dollar amount, *e.g.,* $25,000,000, or some other dollar amount] of the contingent cost, except as provided in paragraph (c) of this section.

(b) In the event the retrospective premium payments assessed from all nuclear suppliers subject to this subpart does not equal the contingent cost owed by the United States, the difference shall be assessed on a pro rata basis consistent with the process in this subpart against those nuclear suppliers that have not reached the cap on premium payments established under paragraph (a) of this section.

(c) If the retrospective premium payments assessed from all nuclear suppliers pursuant to paragraphs (a) and (b) of this section does not equal the contingent cost owed by the United States, then the difference shall be assessed as an additional premium payment on a pro rata basis consistent with the process in this subpart against all nuclear suppliers in an amount necessary to cover the United States' contingent cost in full.

Subpart C—Payments to the United States

§ 951.11 General rule.

Except as provided in § 951.12, not later than 60 calendar days after receipt of a notification from the Department under § 951.4, a nuclear supplier shall pay to the general fund of the Treasury the retrospective premium payment calculated under subpart B of this part.

§ 951.12 Annual payments.

A nuclear supplier may elect to prorate the retrospective premium payment calculated under subpart B of this part in 5 equal annual payments (including interest on the unpaid balance at the prime rate prevailing at the time the first payment is due, no later than 60 days after receipt of a notification from the Department under § 951.4).

§ 951.13 Vouchers.

A nuclear supplier shall make payments required under this Part by submitting a letter, concurrent with payment to the general fund under § 951.11, signed by an official with authority to bind the company to the Secretary of the Treasury that certifies—

(a) The amount paid is made pursuant to the Department's notification under § 951.4;

(b) The amount paid is correctly computed; and

(c) The specific payment plan chosen by the nuclear supplier, either a one-time payment or 5 equal annual payments (including interest on the unpaid balance at the prime rate prevailing at the time the first payment is due, no later than 60 days after receipt of a notification from the Department under § 951.4).

§ 951.14 Failure to pay.

If a nuclear supplier fails to make a payment required under this part, the Secretary shall take appropriate action to recover from the nuclear supplier—

(a) The amount of the payment due from the nuclear supplier;

(b) Any applicable interest on the payment; and

(c) A penalty of not more than twice the amount of the payment due from the nuclear supplier.

Subpart D—Information Collection

§ 951.15 Reporting requirements for prior transactions.

Not later than six months after the effective date of this subpart, a nuclear supplier shall submit electronically a report to the Department signed by an official with authority to bind the company that certifies the following information with respect to each reportable transaction prior to the effective date of this subpart;

(a) Description of the transaction;

(b) Date of the transaction;

(c) Location of nuclear installation(s) involved in the transaction;

(d) Identification of the volume or quantity of each item listed in appendix A or B of this part involved in the transaction; and

(e) Value (expressed in U.S. dollars) of each identified item, and the total value for each reportable transaction.

§ 951.16 Annual reporting requirements.

By March 15 of each year after the effective date of this subpart, a nuclear

supplier shall submit electronically a report to the Department signed by an official with authority to bind the company that certifies the following information with respect to each reportable transaction during the prior calendar year:

(a) Description of the transaction;

(b) Date of the transaction;

(c) Location of the nuclear installation(s) involved in the transaction;

(d) Identification of the volume or quantity of each item listed in appendix A or B of this part involved in the transaction; and

(e) Value (expressed in U.S. dollars) of each identified item.

§ 951.17 Disclosure requirements.

Information received from a nuclear supplier by the Department may be available to the public subject to the provision of 5 U.S.C. 552, 18 U.S.C. 1905 and 10 CFR part 1004, provided that:

(a) Subject to the requirements of law, information such as trade secrets, commercial and financial information that a nuclear supplier may submit to the Department in writing shall not be disclosed in accordance with Department regulations concerning the public disclosure of information. Any nuclear supplier asserting that the information is privileged and confidential should appropriately identify and mark such information when submitting to the Department.

(b) Upon a showing satisfactory to the Department that any information or portion thereof obtained under this regulation would, if made public, divulge trade secrets or other proprietary information, the Department will not disclose such information.

Appendix A to Part 951—List of Primary Nuclear Items

The following are the primary nuclear items to be used in the calculation of the risk exposure of a nuclear supplier. The scope of this appendix includes services for the design, construction, operation, and decommissioning of the nuclear installations identified below, in addition to the supply of the identified components, systems and structures.

1. Nuclear Plant Steam Supply Systems

(a) Reactor pressure vessels, internals, and associated piping, pressure tubes and components, pressurizer, primary steam generators and coolant pumps or circulators.

(b) Nuclear fuel.

(c) On-line reactor fuel charging and discharging machines.

(d) Reactor control rod system, drive mechanisms and rod position indication systems.

(e) Detection, measurement and control equipment to determine neutron flux, temperature and pressure levels of nuclear steam supply systems.

(f) Other components especially designed or prepared for use in a nuclear reactor.

2. Nuclear Plant Safety Systems

(a) Mechanical equipment (*e.g.,* pumps, piping, automatic valves, tanks and heat exchangers).

(b) Emergency electrical equipment including diesel generators, batteries, switchgear and motor control centers.

(c) Associated process monitoring and control equipment.

3. Nuclear Plant Containment

Material and components used to prevent the release of radiation and contamination from the structures housing the nuclear reactor (*e.g.,* in primary containment or confinement buildings).

Appendix B to Part 951—List of Secondary Nuclear Items

The following are secondary nuclear items to be used in the calculation of the risk exposure of a nuclear supplier. The scope of this appendix includes services for the design, construction, operation, and decommissioning of the nuclear installations identified below, in addition to the supply of the identified components, systems and structures.

1. Nuclear Plants

(a) Mechanical equipment including pumps, valves, heat exchangers, cranes, casks, compactors, demineralizers, filters, and tanks.

(b) Electrical equipment including motors, switchgear and motor control centers and batteries.

(c) Process monitoring, detection and control systems.

(d) Structures used for nuclear fuel storage (*e.g.* spent fuel pool and storage racks; dry storage casks and facilities).

2. Enrichment and Fuel Fabrication Facilities

(a) Mechanical equipment including pumps, valves, heat exchangers, cranes, casks, compactors, demineralizers, filters, and tanks.

(b) Electrical equipment including motors, switchgear and motor control centers and batteries.

(c) Process monitoring, detection and control systems.

(d) Gas centrifuges and assemblies and components.

(e) Specially designed or prepared systems, equipment and components for use in various types (gaseous diffusion, centrifuge or laser, etc.) of enrichment plants.

(f) Tanks, casks and structures specifically designed for the storage of nuclear materials.

(g) Nuclear fuel materials (*e.g.,* enriched uranium, plutonium, thorium or mixed oxide fuel).

(h) Fabricated nuclear fuel components (*e.g.,* fuel pellets, fuel pins, fuel assemblies).

3. Irradiated Nuclear Fuel Reprocessing Facility

(a) Mechanical equipment including pumps, valves, heat exchangers, cranes, casks, compactors, demineralizers, filters, and tanks.

(b) Electrical equipment including motors, switchgear and motor control centers and batteries;

(c) Process monitoring, detection and control systems.

(d) Fuel chopping machines (tools intended to cut, chop or shear irradiated fuel).

(e) Dissolvers/Chemical holding or storage tanks.

(f) Solvent extractors/extraction equipment.

(g) Plutonium nitrate to plutonium oxide conversion systems.

(h) Plutonium metal production system.

(i) Tanks, casks and structures specifically designed for the storage of irradiated and separated nuclear material.

4. Nuclear Material Transportation

Casks or canisters especially designed for nuclear material transport.

5. Nuclear Material Storage Facilities

Tanks, casks, and structures specifically designed for the storage of nuclear materials.

Alternative 2—Risk-Informed Assessment Formula by Nuclear Sector

PART 951—CONVENTION ON SUPPLEMENTARY COMPENSATION FOR NUCLEAR DAMAGE CONTINGENT COST ALLOCATION

Subpart A—General Provisions

Sec.

Subpart B—Retrospective Risk Pooling Program

Authority: 42 U.S.C. 2201, 42 U.S.C. 17373.

Subpart A—General Provisions

§ 951.1 Purpose.

This part establishes the regulations for the implementation of section 934 (42 U.S.C. 17373) of the Energy Independence and Security Act of 2007 (Pub. L. 110–140), which provides for the proration of a retrospective premium among nuclear suppliers for the insurance against potential liability for nuclear damage provided by the adherence of the United States to the Convention.

§ 951.2 Scope.

This part covers nuclear incidents that occur outside the United States that result in a request for funds and that are not a Price-Anderson incident.

§ 951.3 Definitions.

For purposes of this part, words shall be defined as provided for in the Atomic Energy Act and in section 934 of the Act and as follows—

Act means the Energy Independence and Security Act of 2007 (Pub. L. 110–140).

Adjusted value means the value (expressed in U.S. dollars) received by a nuclear supplier for an item, adjusted to reflect inflation from the date of the covered transaction involving the item to the date of the nuclear incident for which the retrospective premium payment of the supplier is being calculated.

Contingent cost means the cost to the United States in the event of a covered incident the amount of which is equal to the amount of funds the United States is obligated to make available under paragraph 1(b) of Article III of the Convention.

Convention means the Convention on Supplementary Compensation for Nuclear Damage, done at Vienna on September 12, 1997.

Covered incident means a nuclear incident the occurrence of which results in a request for funds under the Convention.

Covered installation means a nuclear installation at which the occurrence of a nuclear incident could result in a request for funds under the Convention.

Covered nuclear supplier means a nuclear supplier whose goods or services, if supplied in the United States, would be subject to the requirements of 10 CFR part 21.

Covered person means—

(1) A United States person; or

(2) An individual or entity (including an agency or instrumentality of a foreign country) that is located in the United States, or carries out an activity in the United States; but

(3) Does not include the United States, or any agency or instrumentality of the United States.

Covered transaction means any reportable transaction by which a nuclear supplier is the final nuclear supplier of a covered installation, equipment and technology for a covered installation, nuclear materials and transportation of nuclear materials to or from a covered installation, and nuclear services to a covered installation.

Department means the United States Department of Energy.

Final nuclear supplier means the nuclear supplier that obtains, where required, an NRC general or specific license under 10 CFR part 110, Department of Commerce export license under 15 CFR part 734, or DOE authorization under 10 CFR part 810, for the export of the item(s) involved in a reportable transaction.

Lead nuclear supplier means a nuclear supplier whose adjusted value of reportable transactions for the period 1960 through 2007 exceeds $500 million [or some other amount, *e.g.,* $1 billion].

Nuclear installation means:

(1) Any nuclear reactor facility or plant other than one with which a means of sea or air transport is equipped for use as a source of power, whether for propulsion thereof or for any other purpose;

(2) Any facility or plant using nuclear fuel for production of nuclear material, or any facility or plant for the processing of nuclear material, including any facility or plant for the reprocessing of irradiated nuclear fuel; and

(3) Any facility or plant where nuclear material is stored, other than storage incidental to the carriage of such material; provided that the installation State may determine that several nuclear installations of one operator which are located at the same site shall be considered a single nuclear installation.

Nuclear material means nuclear fuel, other than natural or depleted uranium, capable of producing energy by a self-sustaining chain process of nuclear fission outside a nuclear reactor, either alone or in combination with some other material, and radioactive products or waste, where radioactive products or waste means any radioactive material produced in, or any material made radioactive by exposure to the radiation incidental to the production or utilization of nuclear fuel, but does not include radioisotopes which have reached the final stage of fabrication so as to be usable for any scientific, medical, agricultural, commercial or industrial purpose.

Nuclear supplier means a covered person (or a successor in interest of a covered person) that—

(1) Supplies facilities, equipment, fuel, services, or technology pertaining to the design, construction, operation, or decommissioning of a covered installation, or

(2) Transports nuclear materials that could result in a covered incident.

Price-Anderson incident means a covered incident for which section 170 of the Atomic Energy Act of 1954 (42 U.S.C. 2210) would make funds available to compensate for public liability (as defined in section 11 of that Act (42 U.S.C. 2014)).

Reportable transaction means any transaction by a covered nuclear supplier involving supply of the following items: A nuclear installation outside the United States between January 1, 1960 through 2007; equipment, components or technology for a nuclear installation outside the United States after 2007; nuclear materials to a nuclear installation outside the United States after 2007; the transportation outside the United States of nuclear material to or from a nuclear installation after 2007; and the supply of services to a nuclear installation outside the United States after 2007.

Request for funds means a request for funds pursuant to Article VII of the Convention.

Secretary means the Secretary of Energy.

United States means, when used in a geographic sense, the same as the definition of the term in section 11 of the Atomic Energy Act of 1954 and includes the Commonwealth of Puerto Rico, any other territory or possession of

the United States, and the waters of the United States territorial sea under Presidential Proclamation Number 5928, dated December 27, 1988 (43 U.S.C. 1331 note).

United States person means—

(1) Any individual who is a resident, national, or citizen of the United States (other than an individual residing outside of the United States and employed by a person who is not a United States person); and

(2) Any corporation, partnership, association, joint stock company, business trust, unincorporated organization, or sole proprietorship that is organized under the laws of the United States.

Subpart B—Retrospective Risk Pooling Program

§ 951.4 Role of the Department.

Within 60 calendar days of a request for funds, the Department shall calculate the retrospective premium payment for each nuclear supplier in accordance with the rules set forth in this subpart and notify each nuclear supplier through publication in the **Federal Register**.

§ 951.5 Nuclear supplier sectors.

The Department shall calculate the retrospective premium payment for each nuclear supplier based upon the nuclear supplier's covered transactions in the following sectors:

(a) Facility Sector, which consists of the suppliers that are the lead nuclear suppliers involved in the development and deployment of nuclear installations.

(b) Equipment and Technology Sector, which consists of the suppliers of equipment, components or technology used in a nuclear installation.

(c) Nuclear Material and Nuclear Material Transportation Sector, which consists of the suppliers of nuclear materials to a nuclear installation, or the transport of nuclear materials to or from a nuclear installation.

(d) Services Sector, which consists of the suppliers of services to a nuclear installation for the design, construction, operation, or decommissioning of a nuclear installation.

§ 951.6 Retrospective premium payment.

The retrospective premium payment for a nuclear supplier shall be the sum of the product of the risk share of the nuclear supplier by sector and the allocated cost by sector in which the supplier engaged in covered transactions.

§ 951.7 Risk share by sector.

The risk share of a nuclear supplier shall be the quotient of the risk exposure of the nuclear supplier by sector divided by the aggregate risk exposure of all nuclear suppliers in the sector.

§ 951.8 Allocated risk by sector.

The allocation of risk among each of the nuclear sectors is as follows:

(a) Facility sector: 50 percent.

(b) Equipment and Technology sector: 25 percent.

(c) Nuclear Materials and Nuclear Material Transportation sector: 15 percent.

(d) Services sector: 10 percent.

§ 951.9 Allocated cost by sector.

The allocated cost for each sector shall be the product of the allocated risk of each sector and the contingent cost.

§ 951.10 Risk exposure of nuclear supplier in facility sector.

The risk exposure of a nuclear supplier in the facility sector shall be the sum of the following products:

(a) The quantity of all covered transactions by the supplier of nuclear reactor facilities or plants or facilities or plants for the reprocessing of irradiated nuclear fuel multiplied by 2; and

(b) The quantity of all covered transactions by the supplier of facilities or plants for the processing of nuclear material (excluding a nuclear reactor facility or plant or a facility or plant for the reprocessing of irradiated nuclear fuel), facilities or plants where nuclear material is stored (other than storage incidental to the carriage of such material), or nuclear materials transportation multiplied by 1.

§ 951.11 Risk exposure of nuclear supplier in equipment and technology sector.

The risk exposure of a nuclear supplier in the equipment and technology sector shall be the sum of the following products:

(a) The adjusted value of all covered transactions by the supplier of equipment, components or technology for nuclear reactor facilities or plants or facilities or plants for the reprocessing of irradiated nuclear fuel multiplied by 2; and

(b) The adjusted value of all covered transactions by the supplier of equipment, components, or technology for facilities or plants for the processing of nuclear material (excluding a nuclear reactor facility or plant or a facility or plant for the reprocessing of irradiated nuclear fuel), facilities or plants where nuclear material is stored (other than storage incidental to the carriage of such material), or nuclear material transportation multiplied by 1.

§ 951.12 Risk exposure of nuclear supplier in nuclear materials and nuclear materials transportation sector.

The risk exposure of a nuclear supplier in the nuclear materials and nuclear materials transportation sector shall be the sum of the following products:

(a) The quantity in metric tonnage of all covered transactions by the supplier of nuclear materials or nuclear material transportation to nuclear reactor facilities or plants or facilities or plants for the reprocessing of irradiated nuclear fuel multiplied by 2; and

(b) The quantity in metric tonnage of all covered transactions by the supplier of nuclear materials or nuclear material transportation to facilities or plants for the processing of nuclear material (excluding a nuclear reactor facility or plant or a facility or plant for the reprocessing of irradiated nuclear fuel), facilities or plants where nuclear material is stored (other than storage incidental to the carriage of such material), or nuclear material transportation multiplied by 1.

§ 951.13 Risk exposure of nuclear supplier in nuclear services sector.

The risk exposure of a nuclear supplier in the services sector shall be the sum of the following products:

(a) The adjusted value of all covered transactions by the supplier of services to nuclear reactor facilities or plants or facilities or plants for the reprocessing of irradiated nuclear fuel multiplied by 2;

(b) The adjusted value of all covered transactions by the supplier of services to facilities or plants for the processing of nuclear material (excluding a nuclear reactor facility or plant or a facility or plant for the reprocessing of irradiated nuclear fuel), facilities or plants where nuclear material is stored (other than storage incidental to the carriage of such material), and nuclear material transportation multiplied by 1.

§ 951.14 Aggregate risk exposure by sector.

The aggregate risk exposure by sector is the sum of the risk exposures for all nuclear suppliers in that sector.

§ 951.15 Small nuclear supplier exclusion.

A nuclear supplier with a risk exposure of less than [amount, *e.g.,* $1,000,000, or some other amount for covered transactions within the equipment and technology and services sector, and insert amount, *e.g.,* 1,000 MT of nuclear material or some other amount for covered transactions within the nuclear materials and nuclear materials transportation sector, or exclusion for a nuclear supplier that

qualifies as a ''small business'' under Small Business Administration codes] shall not be assessed a retrospective premium payment and shall not be included in the aggregate risk exposure and calculation of retrospective premium payments for other nuclear suppliers.

§ 951.16 Retrospective premium payment cap.

(a) The retrospective premium payment of a nuclear supplier shall not exceed [amount, *e.g.,* 5%, 25%, or some other percentage; or a dollar amount, *e.g.,* $25,000,000, or some other dollar amount] of the contingent cost, except as provided in paragraph (c) of this section.

(b) In the event the retrospective premium payments assessed from all nuclear suppliers subject to this subpart does not equal the contingent cost owed by the United States, the difference shall be assessed on a pro rata basis consistent with the process in this subpart against those nuclear suppliers that have not reached the cap on premium payments established under paragraph (a) of this section.

(c) If the retrospective premium payments assessed from all nuclear suppliers pursuant to paragraphs (a) and (b) of this section does not equal the contingent cost owed by the United States, then the difference shall be assessed as an additional premium payment on a pro rata basis consistent with the process in this subpart against all nuclear suppliers in an amount necessary to cover the United States' contingent cost in full.

Subpart C—Payments to the United States

§ 951.17 General rule.

Except as provided in § 951.18, not later than 60 calendar days after receipt of a notification from the Department under § 951.4, a nuclear supplier shall pay to the general fund of the Treasury the retrospective premium payment calculated under subpart B.

§ 951.18 Annual payments.

A nuclear supplier may elect to prorate the retrospective premium payment calculated under subpart B in 5 equal annual payments (including interest on the unpaid balance at the prime rate prevailing at the time the first payment is due, no later than 60 days after receipt of a notification from the Department under § 951.4).

§ 951.19 Vouchers.

A nuclear supplier shall make payments required under this Part by submitting a letter, concurrent with payment to the general fund under § 951.17, signed by an official with authority to bind the company to the Secretary of the Treasury that certifies –

(a) The amount paid is made pursuant to the Department's notification under § 951.4;

(b) The amount is correctly computed; and

(c) The specific payment plan, either a one-time payment or 5 equal annual payments (including interest on the unpaid balance at the prime rate prevailing at the time the first payment is due, no later than 60 days after receipt of a notification from the Department under § 951.4).

§ 951.20 Failure to pay.

If a nuclear supplier fails to make a payment required under this Part, the Secretary shall take appropriate action to recover from the nuclear supplier—

(a) The amount of the payment due from the nuclear supplier;

(b) Any applicable interest on the payment; and

(c) A penalty of not more than twice the amount of the payment due from the nuclear supplier.

Subpart D—Information Collection

§ 951.21 Reporting requirements for prior transactions.

Not later than six months after the effective date of this subpart, a nuclear supplier shall submit electronically a report to the Department signed by an official with authority to bind the company that certifies the following information with respect to each reportable transaction prior to the effective date of this subpart;

(a) Description of the transaction;

(b) Date of the transaction;

(c) Location of nuclear installation(s) involved in the transaction;

(d) Identification of the volume or quantity of each item involved in the transaction; and

(e) Value (expressed in U.S. dollars) of each identified item, and the total value for each reportable transaction.

§ 951.22 Annual reporting requirements.

By March 15 of each year after the effective date of this subpart, a nuclear supplier shall submit electronically a report to the Department signed by an official with authority to bind the company that certifies the following information with respect to each reportable transaction during the prior calendar year:

(a) Description of the transaction;

(b) Date of the transaction;

(c) Location of the nuclear installation(s) involved in the transaction;

(d) Identification of the quantity of each item involved in the transaction; and

(e) Value (expressed in U.S. dollars) of each identified item involved in the transaction.

§ 951.23 Disclosure requirements.

Information received from a nuclear supplier by the Department may be available to the public subject to the provision of 5 U.S.C. 552, 18 U.S.C. 1905 and 10 CFR part 1004, provided that:

(a) Subject to the requirements of law, information such as trade secrets, commercial and financial information that a nuclear supplier may submit to the Department in writing shall not be disclosed in accordance with Department regulations concerning the public disclosure of information. Any nuclear supplier asserting that the information is privileged and confidential should appropriately identify and mark such information when submitting the information to the Department.

(b) Upon a showing satisfactory to the Department that any information or portion thereof obtained under this regulation would, if made public, divulge trade secrets or other proprietary information, the Department will not disclose such information.

[FR Doc. 2014–29434 Filed 12–16–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0926; Directorate Identifier 2014–NM–085–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 747–8 and 747–8F airplanes. This proposed AD was prompted by an analysis, which determined that in a limited flight envelope with specific conditions, divergent flutter could occur during a high g-load maneuver in combination with certain system failures. This proposed AD would require replacing the lateral control electronic (LCE)

modules, replacing the inboard elevator power control packages (PCPs), installing new external compensators for the PCPs, and revising the maintenance or inspection program. We are proposing this AD to prevent certain system failures from resulting in divergent flutter, and subsequent loss of continued safe flight and landing.

DATES: We must receive comments on this proposed AD by February 2, 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; 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.

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–2014–0926; 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: Douglas Tsuji, Senior Aerospace Engineer, Systems and Equipment Branch, ANM–130S, Seattle Aircraft Certification Office, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6546; fax: 425–917–6590; email: *douglas.tsuji@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–2014–0926; Directorate Identifier 2014–NM–085–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

It was determined by analysis that, within a limited speed/Mach/altitude envelope and with specific payload and fuel conditions, divergent flutter could occur on Model 747–8 and 747–8F airplanes with 0% tail fuel during a high g-load maneuver (>1.6 g) in combination with any of the following system failures:

- Dual hydraulic failure resulting in a free outboard (OB) aileron, free inboard (IB) elevator, and free OB elevator;
- Dual electrical system failure resulting in both OB ailerons free;
- System failures resulting in a free OB aileron;
- System failures resulting in a free IB elevator; and
- Latent excessive IB elevator freeplay.

We are proposing this AD to prevent certain system failures from resulting in divergent flutter, and subsequent loss of continued safe flight and landing.

Relevant Service Information

We reviewed the following service information. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0926.

- Boeing Alert Service Bulletin 747–27A2506, February 3, 2014.
- Boeing Alert Service Bulletin 747–27A2513, Revision 1, dated July 18, 2014.

We have also reviewed Boeing 747–8/8F Certification Maintenance Requirements (CMRs) Document D011U721–02–03, Revision December 2013, which contains the following tasks in Section G., ''CMR Tasks:''

- Item Numbers 27–CMR–10, ''Lubricate inboard elevator hinge bearings.''
- Item Number 27–CMR–11, ''Functional check of inboard elevator hinge bearing and power control unit rod end bearing freeplay.''

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.

Explanation of Applicability, Compliance Time, and Repetitive Intervals

The applicability in paragraph (c) and the compliance times and repetitive intervals in paragraph (i) of this proposed AD are based on airplane utilization. Model 747–8 airplanes referred to as Boeing Business Jets (BBJs) are designated as low utilization airplanes and are maintained under a Boeing Manufacturer's Recommended Program (MRP). The Boeing MRP is limited to airplanes operated less than 1,200 flight hours per calendar year. Therefore, this proposed AD has different implementation task intervals and repetitive intervals for these low utilization airplanes due to unique operations.

Explanation of ''RC'' Steps in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directives Implementation Aviation Rulemaking Committee, to enhance the AD system. One enhancement was a new process for annotating which steps in the service information are required for compliance with an AD. Differentiating these steps from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The actions specified in the service information described previously include steps that are labeled as RC (required for compliance) because these steps have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

As noted in the specified service information, steps labeled as RC must be done to comply with the proposed AD. However, steps that are not labeled as RC are recommended. Those steps that are not labeled as RC may be deviated from, done as part of other actions, or done using accepted methods different from those identified in the service information without obtaining approval of an alternative method of compliance (AMOC), provided the steps labeled as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to steps labeled as RC will require approval of an AMOC.

Costs of Compliance

We estimate that this proposed AD affects 8 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 of LCEs	4 work-hours × $85 per hour = $340	$0	$340	$2,720
Replacement of IB elevator PCPs and installation of external IB elevator compensators.	57 work-hours × $85 per hour = $4,845	44,894	49,739	397,912
Revision to maintenance or inspection program.	1 work-hour × $85 per hour = $85	0	85	680

According to the manufacturer, all 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 airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2014–0926; Directorate Identifier 2014–NM–085–AD.

(a) Comments Due Date

We must receive comments by February 2, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD.

(1) Model 747–8 and 747–8F series airplanes, as identified in Boeing Alert Service Bulletin 747–27A2506, dated February 3, 2014.

(2) Model 747–8 and 747–8F series airplanes, as identified in Boeing Alert Service Bulletin 747–27A2513, Revision 1, dated July 18, 2014.

(3) Model 747–8 series airplanes that are operated less than 1,200 flight hours per calendar year.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Unsafe Condition

This AD was prompted by an analysis, which determined that in a limited flight envelope with specific conditions, divergent flutter could occur during a high g-load maneuver in combination with certain system failures. We are issuing this AD to prevent certain system failures from resulting in divergent flutter, and subsequent loss of continued safe flight and landing.

(f) Compliance

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

(g) Replacement of Lateral Control Electronic (LCE) Modules

For airplanes identified in paragraph (c)(1) of this AD: Within 12 months after the effective date of this AD, replace the LCE modules with new LCE modules having revised software, and do an operational test of the LCE modules, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–27A2506, dated February 3, 2014. If the operational test fails, before further flight, do corrective actions and repeat the operational test and applicable corrective actions until the operational test passes.

(h) Replacement of Inboard Elevator Power Control Packages and Installation of External Inboard Elevator Compensators

For airplanes identified in paragraph (c)(2) of this AD: Within 60 months after the effective date of this AD, replace both

inboard elevator power control packages (PCPs) with new PCPs that have the internal compensators removed, install two larger external compensators for each PCP, and do an operational test of each inboard elevator PCP, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–27A2513, Revision 1, dated July 18, 2014. If the operational test fails, before further flight, do corrective actions and repeat the operational test and applicable corrective actions until the operational test passes.

(i) Revision to the Maintenance or Inspection Program

For all airplanes: Within 90 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate Item Numbers 27–CMR–10, ''Lubricate inboard elevator hinge bearings,'' and 27–CMR–11, ''Functional check of inboard elevator hinge bearing and power control unit rod end bearing freeplay,'' of Section G., ''CMR Tasks,'' of the 747–8/8F Certification Maintenance Requirements (CMRs) Document D011U721–02–03, Revision December 2013. The initial compliance times and repetitive intervals for the lubrication and functional check are specified in paragraphs (i)(1) and (i)(2) of this AD.

(1) For airplanes identified in paragraphs (c)(1) and (c)(2) of this AD that are not identified in paragraph (c)(3) of this AD:

(i) The initial compliance time for the lubrication of the inboard elevator hinge bearings is within 18 months after the most recent lubrication. The repetitive lubrication intervals are specified in Item Number 27–CMR–10, ''Lubricate inboard elevator hinge bearings,'' of Section G., ''CMR Tasks,'' of the 747–8/8F Certification Maintenance Requirements (CMRs) Document D011U721–02–03, Revision December 2013.

(ii) The initial compliance time for the functional check of the inboard elevator hinge bearing and power control unit rod end bearing freeplay is within 12 months after the effective date of this AD. The repetitive functional check intervals are specified in Item Number 27–CMR–11, ''Functional check of inboard elevator hinge bearing and power control unit rod end bearing freeplay,'' of Section G., CMR Tasks, of the 747–8/8F Certification Maintenance Requirements, D011U721–02–03, December 2013.

(2) For airplanes identified in paragraph (c)(3) of this AD:

(i) The initial compliance time for the lubrication of the inboard elevator hinge bearings is within 24 months after the most recent lubrication. Repeat the lubrication thereafter at intervals not to exceed 24 months.

(ii) The initial compliance time for the functional check of the inboard elevator hinge bearing and power control unit rod end bearing freeplay is within 36 months after the effective date of this AD. Repeat the functional check thereafter at intervals not to exceed 36 months.

(j) Parts Installation Prohibition

As of the effective date of this AD, no person may install an LCE having part number (P/N) CA49253–001 or CA49253–002, or an inboard elevator PCP having P/N 327400–1009, on any airplane.

(k) Credit for Actions Accomplished Previously

This paragraph provides credit for the actions required by paragraph (h) of this AD if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 747–27A2513, dated February 4, 2014, which is not incorporated by reference in this AD.

(l) 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 (m)(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.

(4) If the service information contains steps that are labeled as RC (Required for Compliance), those steps must be done to comply with this AD; any steps that are not labeled as RC are recommended. Those steps that are not labeled as RC may be deviated from, done as part of other actions, or done using accepted methods different from those identified in the specified service information without obtaining approval of an AMOC, provided the steps labeled as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to steps labeled as RC require approval of an AMOC.

(m) Related Information

(1) For more information about this AD, contact Doug Tsuji, Senior Aerospace Engineer, Systems and Equipment Branch, ANM–130S, Seattle Aircraft Certification Office, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6546; fax: 425–917–6590; email: *douglas.tsuji@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; 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.

Issued in Renton, Washington, on December 10, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–29484 Filed 12–16–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 81 and 82

[BIA–2014–0006; K00103 12/13 A3A10; 134D0102DR–DS5A300000–DR.5A311.IA000113]

RIN 1076–AE93

Secretarial Election Procedures

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; Extension of comment period.

SUMMARY: This notice announces that the Department of the Interior will extend the comment period on the proposed amending regulations governing Secretarial elections and petitioning procedures to January 16, 2015.

DATES: Comments on the proposed rule published October 9, 2014 (79 FR 61021) must be received by January 16, 2015.

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

—*Federal rulemaking portal: http://www.regulations.gov.* The rule is listed under the agency name ''Bureau of Indian Affairs.'' The rule has been assigned Docket ID: BIA–2014–0006.

—*Email: laurel.ironcloud@bia.gov.* Include ''Part 81'' in the subject line of the message.

—*Mail or hand-delivery:* Chief, Division of Tribal Government Services, Office of Indian Services, Bureau of Indian Affairs, Department of the Interior, 1849 C Street NW., Mail Stop 4513—MIB, Washington, DC 20240.

We cannot ensure that comments received after the close of the comment period (see DATES) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed here will not be included in the docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Ms. Laurel Iron Cloud, Chief, Division of Tribal Government Services, Central

Office, Bureau of Indian Affairs at telephone: (202) 513–7641.

SUPPLEMENTARY INFORMATION: On October 9, 2014, we published a proposed rule amending 25 CFR parts 81 (Secretarial Elections) and 82 (Petitioning Procedures), combining them into one Code of Federal Regulations part at 25 CFR part 81. *See* 79 FR 61021. On October 20, 2014, we published a notice announcing three consultation sessions. See 79 FR 62587.

The proposed rule is available at: *http://www.bia.gov/WhoWeAre/AS-IA/ORM/SecElections/index.htm.*

Dated: December 10, 2014.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2014–29606 Filed 12–16–14; 8:45 am]

BILLING CODE 4310–4J–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2013–0636; FRL–9920–51–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Revision to Allegheny County Rules; Preconstruction Permit Requirements—Nonattainment New Source Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to grant full approval for the revisions to the Commonwealth of Pennsylvania State Implementation Plan (SIP) submitted on June 25, 2012 by the Pennsylvania Department of Environmental Protection (PADEP) on behalf of the Allegheny County Health Department (ACHD). These revisions pertain to ACHD's Nonattainment New Source Review (NNSR) program, and implement an incorporation by reference (IBR) of Pennsylvania's NNSR provisions. They also correct a citation error in ACHD's NNSR regulations. This action is in accordance with the requirements of the Clean Air Act (CAA).

DATES: Written comments must be received on or before January 16, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2013–0636 by one of the following methods:

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

B. *Email: kreider.andrew@epa.gov*.

C. *Mail:* EPA–R03–OAR–2013–0636, Mr. Andrew Kreider, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, 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–2013–0636. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI, or otherwise protected, through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available from the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105; and Allegheny County Health Department, Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: Mr. Paul T. Wentworth, (215) 814–2183, or by email at *wentworth.paul@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On June 25, 2012, PADEP submitted a formal revision to its State Implementation Plan (SIP) (the June 2012 SIP submittal) which revises ACHD's NNSR program. By letter dated June 27, 2014, PADEP modified the June 2012 SIP revision, by withdrawing specific language from the June 2012 SIP submittal. The withdrawn language related to a proposed process for automatically incorporating additions, revisions, or deletions to PADEP's NNSR regulations into ACHD's SIP effective on the date of such PADEP NNSR regulation revision. As a result of PADEP's June 27, 2014 letter, the language withdrawn by PADEP from the June 25, 2012 SIP submission is not being considered as part of this rulemaking action. The remainder of the SIP revision is the subject of this rulemaking action and consists of amendments to ACHD's major NNSR permitting regulations under Article XXI of ACHD's Rules and Regulations. The June 2012 SIP submittal includes amendments to the following sections of ACHD's Rules and Regulations, Article XXI: Section 2102.20 (Definitions); 2102.04 (Installation permits); section 2102.06 (Major sources Locating in or Impacting a Nonattainment Area); and, section 2102.08 (Emissions Offset Registration). As discussed in greater detail in this proposal, the June 2012 SIP submittal includes revisions to ACHD's nonattainment NSR program which are consistent with currently promulgated federal NSR regulations and with NSR regulations which EPA has previously approved into Pennsylvania's SIP.

Generally, the June 2012 SIP revision incorporates provisions related to two Federal rulemaking actions: (a) The 2002 ''Prevention of Significant Deterioration (PSD) and Nonattainment NSR (NSR): Baseline Emissions Determination, Actual-to-Future-Actual

Methodology, Plantwide Applicability Limitations, Clean Units, Pollution Control Projects'' (2002 NSR Reform Rules), see 67 FR 80186, December 31, 2002, and (b) the 2008 ''Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$)'' (2008 NSR $PM_{2.5}$ Rule), see 73 FR 28321, May 16, 2008.

The 2002 NSR Reform Rules made changes to five areas of the NSR programs. In summary, these rules: (1) Provided a new method for determining baseline actual emissions; (2) adopted an actual-to-projected-actual methodology for determining whether a major modification has occurred; (3) allowed major stationary sources to comply with a Plantwide Applicability Limit (PAL) to avoid having a significant emissions increase that triggers the requirements of the major NSR program; (4) provided a new applicability provision for emissions units that are designated clean units; and, (5) excluded pollution control projects (PCPs) from the definition of ''physical change or change in the method of operation.'' On November 7, 2003, EPA published a notice of final action on its reconsideration of the 2002 NSR Reform Rules,[1] which added a definition for ''replacement unit'' and clarified an issue regarding PALs. For additional information on the 2002 NSR Reform Rules, see: (a) EPA's December 31, 2002 final rulemaking action entitled: ''Prevention of Significant Deterioration (PSD) and Nonattainment NSR (NSR): Baseline Emissions Determination, Actual-to-Future-Actual Methodology, Plantwide Applicability Limitations, Clean Units, Pollution Control Projects'' (67 FR 80186), (b) the 2003 final reconsideration: ''Prevention of Significant Deterioration (PSD) and Non-Attainment New Source Review (NSR): Reconsideration'' (68 FR 63021), and (c) the following Web site: *http://www.epa.gov/nsr*.

After the 2002 NSR Reform Rules were finalized and effective (March 3, 2003), industry, state, and environmental petitioners challenged numerous aspects of the 2002 NSR Reform Rules, along with portions of EPA's 1980 NSR Rules (45 FR 52676, August 7, 1980). On June 24, 2005, the United States Court of Appeals for the District of Columbia (DC Circuit) issued a decision on the challenges to the 2002 NSR Reform Rules. *New York* v. *United States,* 413 F.3d 3 (*New York I*).

In summary, the DC Circuit vacated portions of the rules pertaining to clean units and PCPs, remanded a portion of the rules regarding recordkeeping and the term ''reasonable possibility'' found in 40 CFR 52.21(r)(6) and 40 CFR 51.166(r)(6), and either upheld or did not comment on the other provisions included as part of the 2002 NSR Reform Rules. On June 13, 2007 (72 FR 32526), EPA took final action to revise the 2002 NSR Reform Rules to remove from federal law all provisions pertaining to clean units and the PCP exemption that were vacated by the DC Circuit.

The 2008 NSR $PM_{2.5}$ Rule (as well as the 2007 ''Final Clean Air Fine Particle Implementation Rule'' (2007 $PM_{2.5}$ Implementation Rule) [2]), was also the subject of litigation before the DC Circuit in *Natural Resources Defense Council* v. *EPA* (DC Circuit Court decision).[3] On January 4, 2013, the court remanded to EPA both the 2007 $PM_{2.5}$ Implementation Rule and the 2008 NSR $PM_{2.5}$ Rule. The court found that in both rules EPA erred in implementing the 1997 $PM_{2.5}$ NAAQS solely pursuant to the general implementation provisions of subpart 1 of part D of title I of the CAA (subpart 1), rather than pursuant to the additional implementation provisions specific to particulate matter in subpart 4 of part D of title I (subpart 4).[4] As a result, the court remanded both rules and instructed EPA ''to re-promulgate these rules pursuant to subpart 4 consistent with this opinion.'' Although the DC Circuit declined to establish a deadline for EPA's response, EPA intends to respond promptly to the court's remand and to promulgate new generally applicable implementation regulations for the $PM_{2.5}$ NAAQS in accordance with the requirements of subpart 4. In the interim, however, states and EPA still need to proceed with implementation of the 1997 $PM_{2.5}$ NAAQS in a timely and effective fashion in order to meet statutory obligations under the CAA and to assure the protection of public health intended by those NAAQS.

As part of its response to the January 4, 2013 DC Circuit Court of Appeals Order, EPA issued a final rulemaking entitled ''Identification of Nonattainment Classification and Deadlines for Submission of State Implementation Plan (SIP) Provisions for the 1997 Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) and 2006 $PM_{2.5}$ NAAQS; Final Rule,'' (79 FR 31566, June 2, 2014). See *http://www.epa.gov/airquality/particlepollution/actions.html.* This rule classified all existing $PM_{2.5}$ nonattainment areas as ''Moderate'' nonattainment areas and set a deadline of December 31, 2014, for states to submit any SIP submissions, including nonattainment NSR SIPs that may be necessary to satisfy the requirements of subpart 4 with respect to $PM_{2.5}$ nonattainment areas. The existing $PM_{2.5}$ nonattainment areas addressed by this rule included the Liberty-Clairton and Pittsburgh nonattainment areas, portions of which are regulated by ACHD and, therefore, subject to the regulatory revisions being proposed for approval in this action. See 79 FR 31566 (June 2, 2014). EPA is continuing to evaluate the requirements of subpart 4 as they pertain to, among other things, nonattainment NSR for $PM_{2.5}$ emissions.

Additionally, the 2008 NSR $PM_{2.5}$ Rule authorized states to adopt provisions in their nonattainment NSR rules that would allow major stationary sources locating in areas designated nonattainment for $PM_{2.5}$, and major modifications at stationary sources located in areas designated nonattainment for $PM_{2.5}$, to offset emissions increases of direct $PM_{2.5}$ emissions or $PM_{2.5}$ precursors with reductions of either direct $PM_{2.5}$ emissions or $PM_{2.5}$ precursors in accordance with offset ratios contained in the approved SIP for the applicable nonattainment area. The inclusion, in whole or in part, of the interpollutant offset provisions for $PM_{2.5}$ is discretionary on the part of the states. In the preamble to the 2008 NSR $PM_{2.5}$ Rule, EPA included preferred or presumptive offset ratios, applicable to specific $PM_{2.5}$ precursors that a state may adopt in conjunction with the new interpollutant offset provisions for $PM_{2.5}$, and for which a state could rely on the EPA's technical work to demonstrate the adequacy of the ratios for use in any $PM_{2.5}$ nonattainment area. Alternatively, the preamble indicated that states may adopt their own ratios, subject to the EPA's approval, that would have to be substantiated by modeling or other technical demonstrations of the net air quality benefit for ambient $PM_{2.5}$ concentrations. The preferred ratios were subsequently the subject of a petition for reconsideration, which the Administrator granted. EPA continues

[1] *See,* ''Prevention of Significant Deterioration (PSD) and Non-Attainment New Source Review (NSR): Reconsideration;'' (68 FR 63021).

[2] 72 FR 20586 (April 25, 2007)

[3] 706 F.3d 428 (D.C. Cir. 2013)

[4] The court's opinion did not specifically address the point that implementation under subpart 4 requirements would still require consideration of subpart 1 requirements, to the extent that subpart 4 did not override subpart 1. EPA assumes that the court presumed that EPA would address this issue of potential overlap between subpart 1 and subpart 4 requirements in subsequent actions.

to support the basic policy that sources may offset increases in emissions of direct $PM_{2.5}$ or of any $PM_{2.5}$ precursor in a $PM_{2.5}$ nonattainment area with actual emissions reductions in direct $PM_{2.5}$ or $PM_{2.5}$ precursors in accordance with offset ratios as approved in the SIP for the applicable nonattainment area. However, EPA no longer considers the preferred ratios set forth in the preamble to the 2008 $PM_{2.5}$ NSR Rule for $PM_{2.5}$ NSR implementation to be presumptively approvable. Instead, any ratio involving $PM_{2.5}$ precursors adopted by the state for use in the interpollutant offset program for $PM_{2.5}$ nonattainment areas must be accompanied by a technical demonstration that shows the net air quality benefits of such ratio for the $PM_{2.5}$ nonattainment area in which it will be applied.

A Technical Support Document (TSD) is included in the docket for this action, and contains additional detail regarding the history and background of the Federal counterparts to the regulations included in the June 2012 SIP submittal, which will not be restated here.

II. Summary of SIP Revision

The proposed SIP revisions include amendments to ACHD's Rules and Regulations, Article XXI sections: 2102.20 (Definitions), 2102.04 (Installation permits), 2102.06 (Major sources Locating in or Impacting a Nonattainment Area), and 2102.08 (Emissions Offset Registration). The revisions in the June 2012 SIP submittal create a revised NNSR program in Allegheny County which, through amendment and incorporation by reference, reflects all the changes to Pennsylvania's NNSR Program from the revisions to Pennsylvania's SIP approved on May 14, 2012 (NSR reform rules) and on August 13, 2012 (2008 NSR $PM_{2.5}$ rule).

III. Analysis

A. NSR Reform

EPA last took action to approve ACHD's NNSR program into the Pennsylvania SIP on November 14, 2002 (see 67 FR 68935). At that time, a portion of ACHD's approved NNSR program directly relied upon an incorporation by reference of the requirements then codified at 25 PA Code 127.211. In 2007, Pennsylvania revised its NNSR regulations and these revised NNSR regulations were approved into the Pennsylvania SIP on May 14, 2012 (77 FR 28261). These changes added the NSR reform elements into Pennsylvania's NNSR program. However, those changes also deleted section 127.211, and re-codified those requirements elsewhere. That action created a deficiency in ACHD's NNSR provisions, because they relied on the incorporation by reference of a regulatory citation that no longer existed. The June 2012 SIP submittal has incorporated by reference Pennsylvania's NNSR program provisions which are set forth at 25 PA Code Chapter 127 as approved by EPA, including the correct citation at 25 PA Code 127.203a. Because EPA has already approved Pennsylvania's revised NNSR regulations (see 77 FR 28261), there is no need to re-evaluate these same NSR Reform elements which are set forth, or incorporated by reference, in the June 2012 SIP submittal.

EPA has determined that the June 2012 SIP submittal has incorporated all of PADEP's NNSR construction, modification, reactivation, and operating permit program provisions at 25 PA Code section 121.1 and 25 PA Code Chapter 127 (PADEP's NNSR program) and is proposing to approve this submittal as meeting the Federal NNSR requirements.

B. Implementation of NSR Requirements for $PM_{2.5}$

On July 13, 2012, EPA took final action to approve the provisions promulgated in the 2008 NSR $PM_{2.5}$ Rule into the Pennsylvania SIP. See 77 FR 41276. By virtue of the incorporation by reference of Pennsylvania's NNSR regulations, Pennsylvania's June 2012 SIP submittal includes revisions to ACHD's nonattainment NSR program consistent with the provisions promulgated in the 2008 NSR $PM_{2.5}$ Rule and already approved into Pennsylvania's SIP.

EPA is in the process of evaluating the requirements of subpart 4 as they pertain to nonattainment NSR. In particular, subpart 4 includes section 189(e) of the CAA, which requires the control of major stationary sources of PM_{10} precursors (and hence under the DC Circuit court decision, $PM_{2.5}$ precursors) ''except where the Administrator determines that such sources do not contribute significantly to PM_{10} levels which exceed the standard in the area.'' The evaluation of which precursors need to be controlled to achieve the standard in a particular area is typically conducted in the context of the state's preparing and the EPA's reviewing of an area's attainment plan SIP.

While ACHD's submittal may not yet contain all of the elements necessary to satisfy the CAA requirements when evaluated under subpart 4, the proposed revisions represent a considerable strengthening of the currently approved Pennsylvania SIP, which does not currently address $PM_{2.5}$ for Allegheny County. Therefore, EPA is granting full approval to the nonattainment NSR provisions in ACHD's June 2012 SIP.

For the reasons previously discussed, EPA is not evaluating at this time whether ACHD's submittal will require additional revisions to satisfy the subpart 4 requirements. As discussed in section I (Background), by separate rulemaking action, EPA has identified the classification under subpart 4 of areas currently designated nonattainment for the 1997 and 2006 $PM_{2.5}$ NAAQS as ''Moderate.'' These areas include the Liberty-Clairton and Pittsburgh nonattainment areas, portions of which are regulated by ACHD and, therefore, are subject to the regulatory revisions being proposed for approval in this action. That rulemaking also established a December 31, 2014 deadline for the submission of any additional attainment related SIP elements that may be needed to meet the applicable requirements of subpart 4. Therefore, those requirements are not yet due. EPA believes that it is appropriate for the EPA to take into consideration the timing and sequence of related SIP submissions as part of determining what it is reasonable to expect a State to have addressed in a SIP for a NAAQS at the time when the EPA acts on such submission. Such an approach is reasonable, and to adopt a different approach by which the EPA could not approve a SIP, whenever there was any impending or future revision to the SIP that will be required by another collateral rulemaking action would result in regulatory gridlock. The EPA believes that such an outcome would be an unreasonable reading of the statutory process for the SIP's contemplated in section 110(a) (1) and (2).

IV. Proposed Action

EPA is proposing full approval of the June 2012 SIP submittal, which creates a revised NNSR program in Allegheny County.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does

not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, which concerns a revised NNSR program in Allegheny County, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: November 21, 2014.

Shawn M. Garvin,

Regional Administrator, Region III.

[FR Doc. 2014–29579 Filed 12–16–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0008; FRL–9918–90]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before January 16, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNalley, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.,* Susan Lewis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair

treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerance

1. *PP 2F8134.* (EPA–HQ–OPP–2013–0151). Syngenta Crop Protection LLC., P.O. Box 18300, Greensboro, NC 27419–8300, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-hlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on rapeseed, subgroup 20A at 0.1 ppm. For plants, Syngenta Crop Protection, LLC has submitted practical analytical method (AG–575B) for detecting and measuring levels of difenoconazole in or on food with a limit of quantitation (LOQ) that allows monitoring of food with residues at or above the levels set in the proposed tolerances. Residues are qualified by liquid chromatography with tandem mass spectrometry (LC/MS/MS). For livestock, a practical analytical method (AG–544A) for detecting and measuring levels of difenoconazole in or on cattle tissues and milk, and poultry tissues and eggs, with an LOQ that allows monitoring of food with residues at or above the levels set in the proposed tolerances. Tolerances in meat, milk, poultry or eggs were established for enforcement purposes. EPA is republishing this notice of availability.

2. *PP 3E8218.* (EPA–HQ–OPP–2014–0483). BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina, 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, dimethomorph, in or on papaya at 1.5 parts per million (ppm). The analytical method liquid chromatography with LC–MS/MS is available to EPA for the detection and measurement of the pesticide residues. Contact: RD.

3. *PP 3F8199.* (EPA–HQ–OPP–2014–0482). Cheminova A/S, c/o Cheminova, Inc., 1600 Wilson Blvd., Suite 700, Arlington, VA 22209–2510., requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, flutriafol, in or on Brassica, head and stem, subgroup 5A at 1.5 ppm; Brassica, leafy greens, subgroup 5B at 7.0 ppm; egg at 0.01 ppm; hog, liver at 0.05 ppm; hog, meat byproducts, except liver at 0.02 ppm; hog, muscle at 0.01 ppm; leaf petioles, subgroup 4B at 3.0 ppm; leafy greens, subgroup 4A, except head lettuce at 10 ppm; lettuce, head at 1.5 ppm; poultry, meat byproducts at 0.02 ppm; radicchio at 1.5 ppm; sorghum, grain, forage at 2.0 ppm; sorghum, grain, grain at 1.5 ppm; and sorghum, grain, stover at 6.0 ppm. The gas chromatography-mass selective detection (GC/MSD) is used to measure and evaluate the chemical flutriafol. Contact: RD.

4. *PP 3F8213.* (EPA–HQ–OPP–2014–0530). Janssen PMP, Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 08560, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, pyrimethanil, in or on pomegranate (post-harvest) at 5.0 ppm. The high performance liquid chromatography with triple quadruple mass spectrometry (HPLC–MS/MS) is used to measure and evaluate the chemical pyrimethanil. Contact: RD.

5. *PP 3F8224. (*EPA–HQ–OPP–2014–0285). Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide, mandestrobin (S–2200), (2-[(2,5-dimethylphenoxy)methyl]-α-methoxy-*N*-methyl-benzeneacetamide) in or on small fruit vine climbing except fuzzy kiwifruit crop subgroup 13–07F, fruit at 5 ppm; juice at 7 ppm and dried fruit at 10 ppm; low growing berry subgroup 13–07G, fruit at 3 ppm; and rapeseed crop subgroup 20A, seed at 0.6 ppm. An independently validated analytical method has been submitted for analyzing parent S–2200 residues with appropriate sensitivity in all crop commodities for which tolerances are being request. Contact: RD.

6. *PP 4E8232.* (EPA–HQ–OPP–2014–0695). Sumitomo Chemical Company, LTD., 27–1 Shinkawa 2 Chrome, Chuo-Ku, Tokyo 104–8260, Japan, requests to establish an import tolerance in 40 CFR part 180 for residues of the fungicide, diethofencarb (isopropyl 3,4-diethoxycarbanilate), in or on banana at 0.09 ppm. The LC–MS/MS analytical method is used to measure and evaluate the chemical diethofencarb. Contact: RD.

7. *PP 4E8241.* (EPA–HQ–OPP–2014–0232). Interregional Research Project Number 4 (IR–4), 500 College Road East, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the insecticide, novaluron, (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy] phenyl]amino]carbonyl]-2,6-difluorobenzamide), in or on avocado at 0.60 ppm; carrot at 0.05 ppm; bean at 0.60 ppm; vegetable, fruiting, group 8–10 at 1.0 ppm; fruit, pome, group 11–10 at 2.0 ppm; cherry subgroup 12–12A at 8.0 ppm; peach subgroup 12–12B at 1.9 ppm; and plum subgroup 12–12C at 1.9 ppm. The analytical method: Gas chromatography/electron capture detector (GC/ECD) and a high performance liquid chromatography/ultraviolet method (HPLC/UV) with the lowest level of method validation (LLMV) for the subject commodities is 0.05 ppm is used to measure and evaluate the novaluron chemical, residue(s). Contact: RD.

8. *PP 4E8248.* (EPA–HQ–OPP–2014–0284). Interregional Research Project Number 4 (IR–4) 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of S-metolachlor in or on the raw agricultural commodity lettuce at 1.5 parts per million (ppm); vegetable, cucurbit group 9 at 0.50 ppm; vegetable, fruiting, group 8–10, except tabasco pepper at 0.10 ppm; low growing berry subgroup 13–07G except cranberry at 0.40 ppm; and sunflower subgroup 20B at 0.50 ppm and the concurrent deletion of the existing tolerances for okra; vegetable, fruiting, group 8 except tabasco pepper; cucumber; melon subgroup 9A; pumpkin; squash, winter; and sunflower, seed. A gas chromatography-nitrogen phosphorus detection (GC/NPD) method has been submitted to the Agency for determining residues in/on crop commodities and is published in the Pesticide Analytical Manual (PAM) Vol. II, Method I. A GC/MSD method has been submitted to the Agency for determining residues in livestock commodities and is published in PAM Vol. II, Method II. These methods determine residues of S-metolachlor and its metabolites as either CGA–37913 or CGA–49751 following acid hydrolysis. Contact: RD.

9. *PP 4E8250.* (EPA–HQ–OPP–2014–0249). Taminco US Inc., Two Windsor Plaza, Suite 411, 7540 Windsor Drive, Allentown, PA 18195, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide thiram, in or on avocado at 8 ppm. The ALS Laboratory Group method MS 133.02 is used to measure and evaluate the chemical thiram (as CS_2). Contact: RD.

10. *PP 4E8272.* (EPA–HQ–OPP–2014–0496). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540 requests to establish a tolerance in 40 CFR part 180 for residues of fludioxonil [4-(2, 2-difluoro-1,3-benzodioxol-4-yl)-1-H-pyrrole-3-carbonitrile] in or on the raw agricultural commodity carrot at 7.0 ppm. The anaylytical method has passed an Agency petition method validation for several commodities, and is currently the enforcement method for fludioxonil. This method has also been forwarded to the Food and Drug Administration for inclusion into PAM II. An extensive database of method validation data using this method on various crop commodities is available. Contact: RD.

11. *PP 4E8282.* (EPA–HQ–OPP–2014–0397). Interregional Research Project Number 4 (IR–4), 500 College Road East, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, pendimethalin, [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, calculated as the stoichiometric equivalent of pendimethalin, in or on the raw agricultural commodities: Caneberry, sub-group 13–07A at 0.10 ppm; bushberry subgroup 13–07B at 0.10 ppm and by amending the established tolerance in or on the raw agricultural commodities of nut, tree, group 14–12 at 0.10 ppm. The analytical method is aqueous organic solvent extraction, column clean up, and quantitation by GC. The method has a LOQ of 0.05 ppm for pendimethalin and the alcohol metabolite. Contact: RD.

12. *PP 4E8295.* (EPA–HQ–OPP–2014–0552). Interregional Research Project Number 4 (IR–4) 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of esfenvalerate, ((S)-cyano-(3-phenoxyphenyl)methyl (S)-4-chloro-alpha-(1-methylethyl) benzeneacetate in or on the oilseed crop group 20 at 0.5 ppm. The petitioner also requests that upon approval of the tolerance in this petition summary that the existing tolerances for cotton, undelinted seed and sunflower, seed be removed as unnecessary. There is a practical analytical method utilizing electron-capture gas chromatography with nitrogen phosphorous detection available for enforcement with a limit of detection that allows monitoring food with residues at or above tolerance levels. The limit of detection for updated method is the same as that of the current PAM II, which is 0.01 ppm. Contact: RD.

13. *PP 4E8296.* (EPA–HQ–OPP–2013]–0151). Dragonberry Produce/YW International, 386 South Sequoia Parkway, Canby, Oregon 97013, requests to establish a tolerance in 40 CFR 180.475 for residues of the fungicide, difenoconazole, in or on imported dragonfruit at 1.5 ppm. The analytical methods AG–575B for crops and AM–544A for livestock commodities are used to measure and evaluate the chemical difenoconazole residues. Contact: RD.

14. *PP 4F8301.* (EPA–HQ–OPP–2014–0680). Dow AgroSciences LLC, 9330 Zionsville Road; Indianapolis, IN 46268, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, pronamide (propyzamide) and its metabolite containing the 3,5-dichlorobenzoyl moiety calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl) benzamide, in or on lettuce, leaf at 1.0 part per million (ppm). The gas chromatography using electron capture detection method is used to measure and evaluate the chemical pronamide and its metabolite. Contact: RD.

15. *PP 4E8302.* (EPA–HQ–OPP–2014–0590). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540 requests to establish tolerances in 40 CFR part 180 for residues of pyrimethanil (4,6-dimethyl-N- phenyl-2-pyrimidinamine) in or on the raw agricultural commodities cucumber at 1.5 ppm; orange subgroup 10–10A at 10 ppm; lemon subgroup 10–10B at 11 ppm; grapefruit subgroup 10–10C at 10 ppm; fruit, pome, group 11–10 at 14 ppm; fruit, stone, group 12–12 at 10 ppm; and tomato subgroup 8–10A at 0.5 ppm. The petitioner also requests that upon approval of the tolerances in this petition summary, that the tolerances for fruit, citrus, group 10 except lemon, postharvest; lemon, preharvest and postharvest; fruit, pome, group 11 (pre-harvest and post-harvest); fruit, stone, group 12; and tomato be removed as unnecessary. The plant metabolism studies demonstrated that analysis for the parent compound, pyrimethanil is sufficient to enable the assessment of the relevant residues in crop commodities. Pyrimethanil was extracted from cucumbers by homogenization with acetone. After clean-up, an aliquot of the extract was diluted with a mixture of acetonitrile and water with subsequent residue determination by HPLC–MS/MS. The method allows the detection and measurement of residues in or on agricultural commodities at or above the proposed tolerance level. Contact: RD.

16. *PP 4F8281.* (EPA–HQ–OPP–2014–0531). BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, dimethomorph, in or on strawberry at 1.0 ppm. The analytical method LC–MS/MS is available to EPA for the detection and measurement of the pesticide residues. Contact: RD.

17. *PP 4F8286.* (EPA–HQ–OPP–2014–0607). BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709 requests to establish in 40 CFR part 180 for residues of the insecticide metaflumizone ((E and Z isomers; 2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl) phenyl]ethylidene]-N-[4-(trifluormethoxy)phenyl]hydrazine carboxamide)) (CAS No. 139968–49–3) and its metabolite 4-{2-oxo-2-[3-(trifluoromethyl)phenyl]ethyl}-benzonitrile in or on the raw agricultural commodity citrus fruit

group 10–10 at 0.04 ppm; pome fruit group 11–10 at 0.04 ppm; stone fruit group 12–12 at 0.04 ppm; and tree nut group 14–12 at 0.04 ppm. BASF Analytical Method No. 531/0 was developed to determine residues of metaflumizone and its metabolites M320I04 and M320I23 in crop matrices. In this method, residues of metaflumizone are extracted from plant matrices with methanol/water (70:30; v/v) and then partitioned into dichloromethane. For oily matrices, the residues are extracted with a mixture of isohexane/acetonitrile (1:1; v/v). The final determination of metaflumizone and its metabolites is performed by LC/MS/MS. Contact: RD.

Amended Tolerance

1. *PP 3F8199.* (EPA–HQ–OPP–2014–0482). Cheminova A/S, c/o Cheminova, Inc., 1600 Wilson Blvd., Suite 700, Arlington, VA 22209–2510, requests to amend 40 CFR 180.629 by removing tolerances for residues of the fungicide, flutriafol in or on the raw agricultural commodity cotton, meal at 0.5 ppm; cotton, refined oil at 0.5 ppm; hog, meat byproducts at 0.02 ppm. The GC/MSD is used to measure and evaluate the chemical flutriafol. Contact: RD.

2. *PP 3F8199.* (EPA–HQ–OPP–2014–0482). Cheminova A/S, c/o Cheminova, Inc., 1600 Wilson Blvd., Suite 700, Arlington, VA 22209–2510, requests to amend the tolerances in 40 CFR 180.629 for residues of the fungicide, flutriafol in or on the raw agricultural commodity cotton, gin byproducts to 0.5 ppm; cotton, undelinted seed to 0.5 ppm; and grain, aspirated fractions to 6.0 ppm. The GC/MSD is used to measure and evaluate the chemical flutriafol. Contact: RD.

3. *PP 4E8241.* (EPA–HQ–OPP–2014–0232). IR–4, 500 College Road East, Princeton, NJ 08540, proposes upon approval of petitioned-for tolerances listed under ''New Tolerances'', to remove tolerances in 40 CFR 180.598 for residues of the insecticide, novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy] phenyl]amino] carbonyl]-2,6-difluorobenzamide), in or on bean, succulent, snap at 0.60 ppm; bean, dry, seed at 0.30 ppm; cherry at 8.0 ppm; fruit, pome, group 11 at 2.0 ppm; fruit, stone, group 12, except cherry at 1.9 ppm; vegetable, fruiting, group 8 at 1.0 ppm; cocona at 1.0 ppm; African eggplant at 1.0 ppm; pea eggplant at 1.0 ppm; scarlet eggplant at 1.0 ppm; goji berry at 1.0 ppm; garden huckleberry at 1.0 ppm, martynia at 1.0 ppm, naranjilla at 1.0 ppm, okra at 1.0 ppm, roselle at 1.0 ppm; sunberry at 1.0 ppm; bush tomato at 1.0 ppm; currant tomato at 1.0 ppm; and tree tomato at 1.0 ppm. The analytical method: Gas chromatography/electron capture detector (GC/ECD) and a HPLC/UV is used to measure and evaluate novaluron chemical residues. Contact: RD.

4. *PP 4E8268.* (EPA–HQ–OPP–2014–0632). Taminco US Inc., Two Windsor Plaza, Suite 411, 7540 Windsor Drive, Allentown, PA 18195, requests to amend the tolerance in 40 CFR 180.132 for residues of the fungicide thiram, in or on banana at 0.8 ppm. The analytical method #Meth-100, revision #4 is used to measure and evaluate the chemical thiram (as CS_2). Contact: RD.

5. *PP 4E8272.* (EPA–HQ–OPP–2014–0496). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to update an existing crop group in 40 CFR 180.516 for residues of fludioxonil [4-(2, 2-difluoro-1,3-benzodioxol-4-yl)-1-H-pyrrole-3-carbonitrile], by changing ''fruit, stone, group 12 at 5.0 ppm'' to ''fruit, stone, group 12–12 at 5.0 ppm.'' The anaylytical method has passed an Agency petition method validation for several commodities, and is currently the enforcement method for fludioxonil. This method has also been forwarded to the Food and Drug Administration for inclusion into PAM II. An extensive database of method validation data using this method on various crop commodities is available. Contact: RD.

6. *PP 4E8282.* (EPA–HQ–OPP–2014–0397). IR–4, 500 College Road East, Princeton, NJ 08540, proposes upon approval of petitioned-for tolerances listed under ''New Tolerances'', to remove tolerances in 40 CFR 180.361 for residues of the herbicide, pendimethalin, N-(1-ethylpropyl)-3,4-dimethyl-2,6 dinitrobenzenamine, and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on method nut, tree, group 14 at 0.1 ppm; pistachio at 0.1 ppm and juneberry at -0.1 ppm. The analytical method is aqueous organic solvent extraction, column clean up, and quantitation by GC. The method has a LOQ of 0.05 ppm for pendimethalin and the alcohol metabolite. Contact: RD.

7. *PP 4E8302.* (EPA–HQ–OPP–2014–0590). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests that the existing tolerance for ''onion, bulb, subgroup 3–07A'' be changed from 2.0 ppm to 0.20 ppm. The plant metabolism studies demonstrated that analysis for the parent compound, pyrimethanil is sufficient to enable the assessment of the relevant residues in crop commodities. Pyrimethanil was extracted from cucumbers by homogenization with acetone. After clean-up, an aliquot of the extract was diluted with a mixture of acetonitrile and water with subsequent residue determination by HPLC–MS/MS. The method allows the detection and measurement of residues in or on agricultural commodities at or above the proposed tolerance level. Contact: RD.

8. *PP 4F8270.* (EPA–HQ–OPP–2012–0638). BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requests to amend the tolerances in 40 CFR 180.666 for residues of the fungicide, fluxapyroxad (BAS 700 F), 1 *H*-pyrazole-4-carboxamide,3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-, its metabolites, and degradates, in or on cotton, gin byproducts at 20 ppm and cotton undelinted seed at 0.3 ppm. LC/MS/MS method is available as an enforcement method. This method uses reversed-phase HPLC with gradient elution, and includes 2 ion transitions to be monitored for the parent fluxapyroxad (BAS 700 F) plus metabolites M700F008, M700F048. Contact: RD.

9. *PP 4F8281.* (EPA–HQ–OPP–2014–0531). BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina, 27709, requests to amend 40 CFR 180.493 by removing tolerances for residues of the fungicide, dimethomorph (BAS 550 F) [(E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]-morpholine, its metabolites and degradates in or on the raw agricultural commodity lettuce, head at 10 ppm and lettuce, leaf at 10 ppm. The analytical method LC–MS/MS is available to EPA for the detection and measurement of the pesticide residues. Contact: RD.

10. *PP 4F8286.* (EPA–HQ–OPP–2014–0607). BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709 requests to amend 40 CFR 180.657 by removing the established tolerances for residues of the insecticide metaflumizone ((E and Z isomers; 2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl) phenyl]ethylidene]-N-[4-(trifluormethoxy)phenyl] hydrazinecarboxamide)) (CAS No. 139968–49–3) and its metabolite 4-{2-oxo-2-[3-(trifluoromethyl)phenyl]ethyl}-benzonitrile in or on fruit, citrus group 10 at 0.04 ppm and nut, tree, group 14 at 0.04 ppm, upon establishment of the proposed tolerances listed under the ''New Tolerances'' paragraph for PP 4F8286. Contact: RD.

11. *PP 4F8293.* (EPA–HQ–OPP–2014–0613). United Phosphorus, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406, requests to amend the tolerances in 40 CFR 180.293

for residues of the herbicide, endothall, in or on cattle, fat from 0.01 to 0.05 ppm; cattle, kidney from 0.20 to 0.06 ppm; cattle, liver from 0.10 to 0.05 ppm; cattle, meat from 0.03 to 0.05 ppm; goat, fat from 0.005 to 0.05 ppm; goat, kidney from 0.15 to 0.06 ppm; goat, meat from 0.015 to 0.05 ppm; hog, fat from 0.005 to 0.05 ppm; hog, kidney from 0.10 to 0.06 ppm; hog, meat from 0.01 to 0.05 ppm; milk from 0.03 to 0.01 ppm; poultry, fat from 0.015 to 0.05 ppm; poultry, meat from 0.015 to 0.05 ppm; poultry, meat byproducts from 0.2 to 0.05 ppm; sheep, fat from 0.005 to 0.05 ppm; sheep, kidney from 0.15 to 0.06 ppm; and sheep, meat from 0.015 to 0.05 ppm. The analytical method # KP–245R0 using HPLC/MS/MS is used to measure and evaluate the chemical endothall. Contact: RD.

New Tolerance Exemption

1. *PP 3F8221.* (EPA–HQ–OPP–2014–0560). SciReg International on behalf of Andermatt Biocontrol AG., Stahlermatten 6 CH–6146, Grossdietwil, Switzerland, requests to establish an exemption from the requirement of a tolerance for residues of the microbial pesticide, *Bacillus amyloliquefaciens* strain FZB42, in or on all food commodities. The pesticide in intended to control soil borne diseases. The petitioner believes no analytical method is needed because *Bacillus amyloliquefaciens* strain FZB42 is virtually non-toxic and is not pathogenic. Andermatt Biocontrol AG is, therefore, submitting a petition to establish an exemption from the requirement of a tolerance and an analytical method is not required. Contact: BPPD.

2. *PP 4F8251.* (EPA–HQ–OPP–2014–0457). J.R. Simplot Company, 5369 W. Irving St., Boise, IN 83706, requests to establish an exemption from the requirement of a tolerance for residues of the plant incorporated protectant (PIP), Potato Late Blight Resistance Gene (also known as *Rpi-vnt1*), in or on potato. The petitioner believes no analytical method is needed because the petitioner is seeking an exemption from the requirement of a tolerance. Contact: BPPD.

3. *PP 4F8275.* (EPA–HQ–OPP–2014–0454). Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167, requests to establish an exemption from the requirement of a tolerance for residues of the plant-incorporated protectant (PIP), *Bacillus thuringiensis* Cry1A.105 protein, in or on soybean. The petitioner believes no analytical method is needed because the petitioner is seeking an exemption from the requirement of a tolerance. Contact: BPPD.

List of Subjects in 40 CFR Part 180

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 10, 2014.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2014–29428 Filed 12–16–14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2014–0702; FRL–9919–93]

RIN 2070–AB27

Proposed Revocation of Significant New Uses of Metal Salts of Complex Inorganic Acids

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke the significant new use rule (SNUR) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances which were identified generically as metal salts of complex inorganic oxyacids which were the subject of premanufacture notices (PMNs) P–89–576 and P–89–577. EPA issued a SNUR based on a TSCA section 5(e) consent order designating certain activities as significant new uses. EPA has received test data for the chemical substances and is proposing to revoke the SNUR.

DATES: Comments must be received on or before January 16, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0702, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8974; email address: *alwood.jim@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process, or use the chemical substances contained in this proposed rule. 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:

- Manufacturers or processors of the chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. Importers of the chemical, the subject of this action, would no longer be required to certify compliance with the SNUR requirements if the revocation becomes effective. In addition, if this proposed SNUR revocation becomes effective, persons who export or intend to export

the chemical that is the subject of this action would no longer be subject to the TSCA section 12(b)(15 U.S.C. 2611(b) export notification requirements at 40 CFR part 707, that are currently triggered by the SNUR.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

A. What action is the agency taking?

In the **Federal Register** of August 15, 1990 (55 FR 33305) (FRL–3741–8), EPA promulgated a SNUR at 40 CFR 721.4680 for the chemical substances identified generically as metal salts of complex inorganic oxyacids (PMNs P–89–576 and P–89–577). That SNUR designated certain activities as significant new uses based on a TSCA section 5(e) consent order for the PMNs that was issued under TSCA sections 5(e)(1)(A)(i), and 5(e)(1)(A)(ii)(II) based on a finding that the chemical substances may be produced in substantial quantities and there may be significant (or substantial) human exposure to the chemical substances. EPA has received human health testing for the chemical substances and, based on its review of these data, EPA now proposes to revoke the SNUR pursuant to § 721.185. In this unit, EPA provides a brief description of these chemical substances, including the PMN numbers, generic chemical names, the **Federal Register** publication date and citation, the docket ID number, the basis for revoking the SNUR under § 721.185, and the CFR citation of the SNUR.

PMN Numbers P–89–576 and P–89–577

Chemical name: Metal salts of complex inorganic oxyacids (generic).

CAS number: Not available.

Federal Register *publication date and citation:* August 15, 1990 (55 FR 33305).*Basis for revocation of SNUR:* EPA issued a SNUR for these chemical substances that designated certain activities as significant new uses based on a TSCA section 5(e) consent order for the PMNs that was issued under TSCA sections 5(e)(1)(A)(i), and 5(e)(1)(A)(ii)(II) based on a finding that the chemical substances may be produced in substantial quantities and there may be significant (or substantial) human exposure to the chemical substances. The SNUR required notification before exceeding the production volume limit in the TSCA section 5(e) consent order. Subsequently, a manufacturer of the chemical substances petitioned EPA to revoke the SNUR based on the results of the submitted acute dermal study and a 28-day oral toxicity study, for P–89–576 which demonstrated no adverse health effects. Based on the results of the testing, EPA determined that both substances have inherently low toxicity. Therefore, EPA finds that for activities involving the chemical substances that have been designated as significant new uses pending the completion of testing, adequate test data developed in accordance with applicable procedures and criteria have been submitted to EPA. Therefore, EPA proposes that the SNUR for these chemical substances be revoked pursuant to § 721.185(a)(6).

CFR citation: 40 CFR 721.4680

B. What is the agency's authority for taking this action?

Upon conclusion of the review for P–89–576 and P–89–577 in 1990, EPA designated certain activities as significant new uses based on a TSCA section 5(e) consent order for the PMNs that was issued under TSCA sections 5(e)(1)(A)(i), and 5(e)(1)(A)(ii)(II) based on a finding that the chemical substances may be produced in substantial quantities and there may be significant (or substantial) human exposure to the chemical substances. Under § 721.185, EPA may at any time revoke a SNUR for a chemical substance which has been added to subpart E of 40 CFR part 721 if EPA makes one of the determinations set forth in § 721.185(a)(1) through (6). Revocation may occur on EPA's initiative or in response to a written request. Under § 721.185(b)(3), if EPA concludes that a SNUR should be revoked, the Agency will propose the changes in the **Federal Register**, briefly describe the grounds for the action, and provide interested parties an opportunity to comment.

EPA has determined that the criteria set forth in § 721.185(a)(6) have been satisfied for the chemical substances; therefore, EPA is proposing to revoke the SNUR for these chemical substances. The significant new use notification and the recordkeeping requirements at 40 CFR 721.4680 would terminate if and when this proposed revocation becomes effective. In addition, export notification under TSCA section 12(b) and 40 CFR part 707, subpart D, triggered by the SNUR would no longer be required.

III. Statutory and Executive Order Reviews

This proposed rule would revoke or eliminate an existing regulatory requirement and does not contain any new or amended requirements. As such, the Agency has determined that this proposed SNUR revocation would not have any adverse impacts, economic or otherwise.

The Office of Management and Budget (OMB) has exempted these types of regulatory actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). This action does not contain any information collections subject to approval under the Paperwork Reduction Act (PRA), (44 U.S.C.3501 *et seq.*). Since this action eliminates a reporting requirement, the Agency certifies pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C.601 *et seq.*), that this SNUR revocation would not have a significant economic impact on a substantial number of small entities.

For the same reasons, this action does not require any action under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*) (Pub.L. 104–4). This action has neither Federalism implications, because it would not have substantial direct effects on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 entitled ''Federalism'' (64 FR 43255, August 10, 1999), nor Tribal implications, because it would not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in Executive Order 13175 entitled ''Consultation and Coordination

with Indian Tribal Governments'' (65 FR 67249, November 9, 2000).

This action is not subject to Executive Order 13045 entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined under Executive Order 12866, and it does not address environmental health or safety risks disproportionately affecting children. This action is not subject to Executive Order 1311, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use. Because this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), section 12(d) (15 U.S.C. 272 note), does not apply to this action. This action does not involve special considerations of environmental justice related issues as required by Executive Order 12898 entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 11, 2014.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

§ 721.4680 [Removed]

■ 2. Remove § 721.4680.

[FR Doc. 2014–29575 Filed 12–16–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 12–271; RM–11678; DA 14–1683]

Radio Broadcasting Services; Pike Road, AL

AGENCY: Federal Communications Commission.

ACTION: Proposal rule; denial.

SUMMARY: The Audio Division denies the Petition for Rule Making filed by Alatron Corporation, Inc., proposing the allotment of FM Channel 228A at Pike Road, Alabama. The petition was denied because a counterproposal, consisting of three minor change applications, was granted instead: Application of Southeast Alabama Broadcasters, LLC, to upgrade the facilities of Station WDLA(FM), to 280C2, Fort Rucker, Alabama. The application of Gulf South Communications, Inc., to change the community of license for Station WDJR(FM), to Hartford, Alabama, and the application of Gulf South Communications, Inc., to change the channel and community of license for Station WDBT(FM), to Channel 228A, Hope Hull, Alabama. The license for Station WAAO–FM, Andalusia, Alabama will be modified to specify operation on Channel 229A.

DATES: This is a synopsis of the Report and Order, MB Docket No. 12–271, adopted November 20, 2014, and released November 21, 2014.

FOR FURTHER INFORMATION CONTACT: Deborah A. Dupont, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Report and Order, MB Docket No. 12–271, adopted November 20, 2014, and released November 21, 2014. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or via email *www.BCPIWEB.com.* This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. This document is not subject to the Congressional Review Act. (The Commission is not required to submit a copy of this Report and Order to Government Accountability Office, pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because no rule changes were made).

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2014–29446 Filed 12–16–14; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 79, No. 242
Wednesday, December 17, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Adoption of Recommendations

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: The Administrative Conference of the United States adopted three recommendations at its Sixty-First Plenary Session. The appended recommendations address: Retrospective Review of Agency Rules; Petitions for Rulemaking; and Best Practices for Using Video Teleconferencing for Hearings.

FOR FURTHER INFORMATION CONTACT: For Recommendation 2014–5, Reeve Bull; for Recommendation 2014–6, Emily Bremer; and for Recommendation 2014–7, Amber Williams. For all three of these actions the address and telephone number are: Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW., Washington, DC 20036; Telephone 202–480–2080.

SUPPLEMENTARY INFORMATION: The Administrative Conference Act, 5 U.S.C. 591–596, established the Administrative Conference of the United States. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by Federal agencies and makes recommendations to agencies, the President, Congress, and the Judicial Conference of the United States for procedural improvements (5 U.S.C. 594(1)). For further information about the Conference and its activities, see *www.acus.gov.* At its Sixty-First Plenary Session, held December 4–5, 2014, the Assembly of the Conference adopted three recommendations.

Recommendation 2014–5, *Retrospective Review of Agency Rules.* This recommendation examines agencies' procedures for reanalyzing and amending existing regulations and offers recommendations designed to promote a culture of retrospective review at agencies. Among other things, it urges agencies to plan for retrospective review when drafting new regulations; highlights considerations germane to selecting regulations for reevaluation; identifies factors relevant to ensuring robust review; and encourages agencies to coordinate with the Office of Management and Budget, other agencies, and outside entities (including stakeholders and foreign regulators) when designing and conducting retrospective reviews.

Recommendation 2014–6, *Petitions for Rulemaking.* This recommendation identifies agency procedures and best practices for accepting, processing, and responding to petitions for rulemaking. It seeks to ensure that the public's right to petition is a meaningful one, while still respecting the need for agencies to retain decisional autonomy. Building upon ACUS's previous work on the subject, it provides additional guidance that may make the petitioning process more useful for agencies, petitioners, and the public.

Recommendation 2014–7, *Best Practices for Using Video Teleconferencing for Hearings.* This recommendation offers practical guidance regarding how best to conduct video hearings, and addresses the following subjects: Equipment and environment, training, financial considerations, procedural practices, fairness and satisfaction, and collaboration among agencies. It also provides for the development of a video hearings handbook by ACUS's Office of the Chairman.

The Appendix below sets forth the full texts of these three recommendations. The Conference will transmit them to affected agencies, Congress, and the Judicial Conference of the United States. The recommendations are not binding, so the entities to which they are addressed will make decisions on their implementation.

The Conference based these recommendations on research reports that are posted at: *www.acus.gov/61st.* A video of the Plenary Session is available at: *new.livestream.com/ACUS/61stPlenarySession,* and a transcript of the Plenary Session will be posted when it is available.

Dated: December 12, 2014.

Shawne C. McGibbon,

General Counsel.

Appendix—Recommendations of the Administrative Conference of the United States

Administrative Conference Recommendation 2014–5

Retrospective Review of Agency Rules

Adopted December 4, 2014

Executive Summary

The following recommendation is intended to provide a framework for cultivating a ''culture of retrospective review'' within regulatory agencies. It urges agencies to remain mindful of their existing body of regulations and the ever-present possibility that those regulations may need to be modified, strengthened, or eliminated in order to achieve statutory goals while minimizing regulatory burdens. It encourages agencies to make a plan for reassessing existing regulations and to design new regulations in a way that will make later retrospective review easier and more effective. It recognizes that input from stakeholders is a valuable resource that can facilitate and improve retrospective review. Finally, it urges agency officials to coordinate with other agencies and the Office of Management and Budget to promote coherence in shared regulatory space.

Preamble

Traditionally, federal regulatory policymaking has been a forward-looking enterprise: Congress delegates power to administrative agencies to respond to new challenges, and agencies devise rules designed to address those challenges. Over time, however, regulations may become outdated, and the cumulative burden of decades of regulations issued by numerous federal agencies can both complicate agencies' enforcement efforts and impose a substantial burden on regulated entities. As a consequence, Presidents since Jimmy Carter have periodically undertaken a program of ''retrospective review,'' urging agencies to reassess regulations currently on the books and eliminate, modify, or strengthen those regulations that have become outmoded in light of changed circumstances.[1] Agencies have also long been subject to more limited regulatory lookback requirements, including the Regulatory Flexibility Act, which requires agencies to review regulations having ''a significant economic impact upon a substantial number of small entities''[2]

[1] Joseph E. Aldy, *Learning from Experience: An Assessment of Retrospective Reviews of Agency Rules & the Evidence for Improving the Design & Implementation of Regulatory Policy 4* (Nov. 17, 2014), available at *http://www.acus.gov/report/retrospective-review-report.*

[2] 5 U.S.C. 610.

within ten years of issuance, and program-specific retrospective review requirements erected by statute.[3]

Though historical retrospective review efforts have resulted in some notable successes,[4] especially in those instances in which high-level leadership in the executive branch and individual agencies has strongly supported these endeavors,[5] retrospective review of regulations has not been held to the same standard as prospective review, and the various statutory lookback requirements apply only to subsets of regulations. President Barack Obama has sought to build on these initiatives in several executive orders. On January 18, 2011, he issued Executive Order (E.O.) 13,563,[6] which directed executive branch agencies regularly to reassess existing rules to identify opportunities for eliminating or altering regulations that have become ''outmoded, ineffective, insufficient, or excessively burdensome.'' [7] Shortly thereafter, he issued another order encouraging independent regulatory agencies to pursue similar regulatory lookback efforts (E.O. 13,579 [8]) and yet another order providing a more detailed framework for retrospective review in executive branch agencies (E.O. 13,610 [9]).

The Administrative Conference has long endorsed agencies' efforts to reevaluate and update existing regulations. In 1995, the Conference issued a recommendation stating that ''[a]ll agencies (executive branch or 'independent') should develop processes for systematic review of existing regulations to determine whether such regulations should be retained, modified or revoked'' and offering general guidance by which agencies might conduct that analysis.[10] In addition, in early 2011, shortly after the promulgation of EO 13,563, the Conference hosted a workshop designed to highlight best practices for achieving the EO's goals.[11]

Administrative law scholars and other experts have debated the effectiveness of existing retrospective review efforts. E.O. 13,610 touts the elimination of ''billions of dollars in regulatory costs and tens of millions of hours in annual paperwork burdens'' achieved under the EO 13,563 framework and promises additional savings.[12] Cass Sunstein, the former Administrator of the Office of Information and Regulatory Affairs (OIRA), has suggested that these initiatives have yielded billions of dollars in savings.[13] Nevertheless, many criticize the existing system of regulatory lookback as inadequate, especially insofar as it relies upon individual agencies to reassess their own regulations and provides few incentives for ensuring robust analysis of existing rules.[14] From the opposite perspective, many criticize current retrospective review efforts as inherently deregulatory, possessing a strong bias in favor of eliminating or weakening regulations rather than strengthening regulations that may be insufficiently protective.[15]

Ultimately, a system of ''self-review,'' in which individual agencies are responsible for evaluating their own regulations and, to the extent permitted by law, modifying, strengthening, or eliminating those that are deemed to be outdated, can only succeed if agencies promote a ''culture of retrospective review.'' [16] Without a high-level commitment, any regulatory lookback initiative runs the risk of devolving into an exercise of pro forma compliance. This might not be an inevitable outcome, however. If the relevant agency officials, including both those conducting retrospective reviews and those drafting new rules, come to view regulation as an ongoing process whereby agency officials recognize the uncertainty inherent in the policymaking exercise and continually reexamine their regulations in light of new information and evolving circumstances, a durable commitment can emerge.[17] Regulatory review should not only be a backward-looking exercise; rather, it should be present from the beginning as part of an on-going culture of evaluation and iterative improvement. Planning for reevaluation and regulatory improvement (including defining how success will be measured and how the data necessary for this measurement will be collected) should be considered an integral part of the development process for appropriate rules. This culture of evaluation and improvement is already part of many government programs, but not yet of most regulatory programs.

This recommendation aims to help agencies create such a culture of retrospective review. To promote robust retrospective analysis, agency officials must see it as critical to advancing their missions. To obtain this ''buy-in,'' these officials must have a framework for performing the required analysis and possess adequate resources for conducting the necessary reviews (such that doing so is wholly integrated into agencies' other responsibilities rather than serving to displace those existing responsibilities). Given the costs of performing robust retrospective analysis, it is critical that agencies have adequate resources such that conducting retrospective review does not detract from other aspects of their regulatory missions. Thus, the recommendation sets forth considerations relevant both to identifying regulations that are strong candidates for review and for conducting retrospective analysis.[18] In addition, the recommendation encourages agencies to integrate retrospective analysis into their policymaking framework more generally, urging them not only to reevaluate existing regulations but also to design new regulations with an eye towards later reexamination and to consider the cumulative regulatory burden. In doing so, agencies should identify data collection needs and consider other regulatory drafting strategies that can help them later determine whether the regulation achieved its purpose.[19] Finally, the recommendation identifies opportunities for conserving agency resources by taking advantage of

[3] Aldy, *supra* note 1, at 4.

[4] *See generally* Martha Derthick & Paul J. Quirk, The Politics of Deregulation (1985).

[5] *See generally* John Kamensky, National Partnership for Reinventing Government: A Brief History (Jan. 1999), available at *http://govinfo.library.unt.edu/npr/whoweare/history2.html* (highlighting the successes of the Clinton Administration's National Performance Review and emphasizing the importance of high-level executive branch and agency leadership).

[6] 76 FR 3821 (Jan. 21, 2011).

[7] *Id.* § 6.

[8] 76 FR 41587 (July 14, 2011).

[9] 77 FR 28469 (May 14, 2012).

[10] Administrative Conference of the United States, Recommendation 95–3, *Review of Existing Agency Regulations,* 60 FR 43108, 43109 (Aug. 18, 1995).

[11] Administrative Conference of the United States, Retrospective Review of Existing Regulations, Workshop Summary (Mar. 10, 2011), *http://www.acus.gov/fact-sheet/retrospective-review-workshop-summary.*

[12] Exec. Order No. 13,610, § 1, 77 FR 28469, 28469 (May 14, 2012).

[13] Cass R. Sunstein, Simpler: The Future of Government 180–84 (2013) (highlighting successful retrospective review efforts, including a Department of Health and Human Services reform to reporting requirements saving $5 billion over five years and a Department of Labor rule to harmonize hazard warnings with the prevailing international practice saving $2.5 billion over five years); *see also* Memorandum from President Ronald Reagan on the Review of Federal Regulatory Programs (Dec. 15, 1986) (describing the results of the Presidential Task Force on Regulatory Relief, which included ''substantial changes to over 100 existing burdensome rules'' that ''sav[ed] businesses and consumers billions of dollars each year'').

[14] *See, e.g.,* Reeve T. Bull, *Building a Framework for Governance: Retrospective Review & Rulemaking Petitions,* __ Admin. L. Rev. __ (forthcoming 2015); Cary Coglianese, *Moving Forward with Regulatory Lookback,* 30 Yale J. on Reg. 57A, 60A (2013); Michael Mandel & Diana G. Carew, Progressive Policy Institute Policy Memo, *Regulatory Improvement Commission: A Politically Viable Approach to U.S. Regulatory Reform* 13 (May 2013).

[15] *See, e.g.,* Michael A. Livermore & Jason A. Schwarz, *Unbalanced Retrospective Regulatory Review,* Penn Program on Regulation RegBlog, July 12, 2012, *http://www.regblog.org/2012/07/12-livermore-schwartz-review.html;* Rena Steinzor, *The Real ''Tsunami'' in Federal Regulatory Policy, CPRBlog,* May 22, 2014, *http://www.progressivereform.org/CPRBlog.cfm?idBlog=2480725C-9CC8-717D-E8DE6C4C4A5FF6EB.*

[16] Aldy, *supra* note 1, at 47–48; Coglianese, *supra* note 14, at 66A.

[17] Aldy, *supra* note 1, at 47–48.

[18] In 2011, the Conference recommended that agencies periodically review regulations that have incorporated by reference material published elsewhere in order to ensure that they are updated as appropriate and contain complete and accurate access information. Administrative Conference of the United States, Recommendation 2011–5, *Incorporation by Reference,* ¶¶ 6–10, 77 FR 2257, 2259 (Jan. 17, 2012).

[19] Some scholars propose the use of experimental methods and data-driven evaluation techniques in order to identify the actual impacts caused by regulations and determine whether they are achieving their intended outcomes. John DiNardo & David S. Lee, *Program Evaluation & Research Designs, in* 4A Handbook of Labor Economics 463–536 (2011); *see also generally* Joseph S. Wholey, Harry P. Hatry, & Kathryn E. Newcomer, Handbook of Practical Program Evaluation (3d ed. 2010). This might include, among other things, taking the opportunity of pilot projects and regulatory phase-ins to test different regulatory approaches. Some scholars also propose the use of alternative regulatory mechanisms and other innovative approaches designed to lessen regulatory burdens while ensuring appropriate levels of regulatory protection.

internal and external sources of information and expertise. In many instances, stakeholders may be able to furnish information to which agency officials otherwise lack access.[20] In other cases, overseas regulators may have confronted similar regulatory problems, and incorporating these approaches would have the double benefit of avoiding duplication of effort and providing opportunities for eliminating unnecessary regulatory divergences.[21] Further, the information generated from retrospective review has the potential to conserve resources during future regulatory development of similar rules by informing ex ante regulatory analysis, which in turn improves the quality of new regulations.[22]

Though the recommendation identifies certain common principles and opportunities for promoting robust retrospective analysis, it accepts the fact that each agency must tailor its regulatory lookback procedures to its statutory mandates, the nature of its regulatory mission, its competing priorities, and its current budgetary resources. In short, retrospective review is not a ''one-size-fits-all'' enterprise. In addition, as optimal regulatory approaches may evolve over time, so too may retrospective review procedures. Therefore, the recommendation avoids an overly rigid framework. Rather, it identifies considerations and best practices that, over time, should help foster a regulatory approach that integrates retrospective analysis as a critical element of agency decisionmaking and that accounts for the uncertainty inherent in regulatory policymaking at all stages of the process. The overall goal is to move away from a model of retrospective analysis as an episodic, top-down reporting and compliance obligation to one where agencies internalize a culture of retrospective review as part of their general regulatory mission.

Recommendation

Value of Retrospective Review

1. The Conference endorses the objectives of Executive Orders 13,563, 13,579, and 13,610 with respect to retrospective review of existing regulations. Agencies should work with the Office of Management and Budget (OMB), as appropriate, to develop retrospective review into a robust feature of the regulatory system.

Integrating Retrospective Review Into New Regulations

2. When formulating new regulations, agencies should, where appropriate, given available resources, priorities, authorizing statutes, nature of the regulation, and impact of the regulation, establish a framework for reassessing the regulation in the future and should consider including portions of the framework in the rule's preamble. The rigor of analysis should be tailored to the rule being reviewed. The agencies should consider including the following in the framework:

(a) The methodology by which they intend to evaluate the efficacy of and the impacts caused by the regulation, including data-driven experimental or quasi-experimental designs where appropriate, taking into account the burdens to the public in supplying relevant data to agencies.

(b) A clear statement of the rule's intended regulatory results with some measurable outcome(s) and a plan for gathering the data needed to measure the desired outcome(s). To the extent feasible, objectives should be outcome-based rather than output-based. Objectives may include measures of both benefits and costs (or cost-effectiveness), as appropriate.

(c) Key assumptions underlying any regulatory impact analysis being performed on the regulation. This should include a description of the level of uncertainty associated with projected regulatory costs and benefits, consistent with OMB Circular A–4.

(d) A target time frame or frequency with which they plan to reassess the proposed regulation.

(e) A discussion of how the public and other governmental agencies (federal, state, tribal, and local) will be involved in the review.

Agencies that have systematic review plans available on the internet that set forth the process and a schedule for their review of existing rules may address the recommendations in subparagraphs (a)–(e), as appropriate, by reference to their plans.

3. When reviewing new regulations, the Office of Information and Regulatory Affairs (OIRA) should facilitate planning for subsequent retrospective review to the extent appropriate. Agencies should consider including a section in the preamble of their proposed and final rules that accounts separately for paperwork burdens associated with the collection of data to facilitate retrospective review and should note that data gaps can impede subsequent retrospective review (though the paperwork burden would still be included in the total cost of the instant rule).

4. Where it is legally permissible and appropriate, agencies should consider designing their regulations in ways that allow alternative approaches in the rule that could help the agency in a subsequent review of the rule to determine whether there are more effective approaches to implementing its regulatory objective. For example, agencies could allow for experimentation, innovation, competition, and experiential learning (calling upon the insights of internal statistical offices, as well as policy and program evaluation offices, in order to design plans for reassessing regulations, to the extent they have such resources). As recommended by OMB Circular A–4, agencies should consider allowing states and localities greater flexibility to tailor regulatory programs to their specific needs and circumstances and, in so doing, to serve as a natural experiment to be evaluated by subsequent retrospective review. Statutes that authorize shared responsibility among different levels of government may be amenable to such flexibility.

Prioritizing Regulations for Retrospective Analysis

5. In light of resource constraints and competing priorities, agencies should adopt and publicize a framework for prioritizing rules for retrospective analysis. Agency frameworks should be transparent and enable the public to understand why the agency prioritized certain rules for review in light of the articulated selection criteria. Though considerations will vary from agency to agency and program to program, the following factors can help identify strong candidates for retrospective review that could inform regulatory revision:

(a) Likelihood of improving attainment of statutory objective;

(b) Likelihood of increasing net benefits and magnitude of those potential benefits;

(c) Uncertainty about the accuracy of initial estimates of regulatory costs and benefits;

(d) Changes in the statutory framework under which the regulation was issued;

(e) Cumulative regulatory burden created by the regulation at issue and related regulations (including those issued by other agencies);

(f) Changes in underlying market or economic conditions, technological advances, evolving social norms, public risk tolerance, and/or standards that have been incorporated by reference;

(g) Internal agency administrative burden associated with the regulation;

(h) Comments, petitions, complaints, or suggestions received from stakeholder groups and members of the public;

(i) Differences between U.S. regulatory approaches and those of key international trading partners;

(j) Complexity of the rule (as demonstrated by poor compliance rates, amount of guidance issued, remands from the courts, or other factors); and

(k) Different treatment of similarly situated persons or entities (including both regulated parties and regulatory beneficiaries).

To the extent applicable, agencies should consider both the initial estimates of regulatory costs and benefits, and any additional evidence suggesting that those estimates are no longer accurate.

6. Though agencies will likely focus their retrospective analysis resources primarily on important regulations as identified by the foregoing factors, they should also take advantage of simple opportunities to improve

[20] Aldy, *supra* note 1, at 25–26, 70–71; *see generally* Bull, *supra* note 14 (proposing a system whereby private entities would use petitions for rulemaking to urge agencies to adopt less burdensome alternatives to existing regulations while preserving existing levels of regulatory protection). Agencies should nevertheless recognize that private and non-governmental entities' interests may not align with public interests and that established firms may actually defend regulations that create barriers to entry for newer, smaller competitors. Susan E. Dudley & Jerry Brito, Regulation: A Primer 18–19 (2d ed. 2012) (describing the so-called ''bootleggers and Baptists'' phenomenon, whereby businesses that benefit from market interventions may make common cause with civil society groups that advocate such policies for other reasons).

[21] Exec. Order No. 13,609, § 1, 77 FR 26413, 26413 (May 4, 2012); Administrative Conference of the United States, Recommendation 2011–6, *International Regulatory Cooperation,* ¶ 4, 77 FR 2259, 2260 (Jan. 17, 2012).

[22] Peter H. Schuck, Why Government Fails So Often and How It Can Do Better 57 (2014).

regulations when the changes are relatively minor (*e.g.,* allowing electronic filing of forms in lieu of traditional paper filing).

Performing Retrospective Analysis

7. When conducting retrospective analysis of existing regulations, agencies should consider whether the regulations are accomplishing their intended purpose or whether they might, to the extent permitted by law, be modified, strengthened, or eliminated in order to achieve statutory goals more faithfully, minimize compliance burdens on regulated entities, or more effectively confer regulatory benefits. The level of rigor of retrospective analysis will depend on a variety of factors and should be tailored to the circumstances. As appropriate and to the extent resources allow, agencies should employ statistical tools to identify the impacts caused by regulations, including their efficacy, benefits, and costs and should also consider the various factors articulated in recommendation 5 in determining how regulations might be modified to achieve their intended purpose more effectively.

8. Agencies should consider assigning the primary responsibility for conducting retrospective review to a set of officials other than those responsible for producing or enforcing the regulation, if adequate resources are available. Reviewing officials should coordinate and collaborate with rule producers and enforcers.

9. Agencies should periodically evaluate the results of their retrospective reviews and determine whether they are identifying common problems with the effectiveness of their rule development and drafting practices that should be addressed.

Inter-Agency Coordination

10. Agencies should coordinate their retrospective reviews with other agencies that have issued related regulations in order to promote a coherent regulatory scheme that maximizes net benefits. Agencies and OMB should also consider creating a high-level organization responsible for promoting coordination between agencies in their retrospective review efforts (or assigning this function to an existing entity, such as the Regulatory Working Group).

11. In conducting retrospective review, agencies should consider regulations adopted by key trading partners and examine the possibility of either harmonizing regulatory approaches or recognizing foreign regulations as equivalent to their U.S. counterparts when doing so would advance the agency mission or remove an unnecessary regulatory difference without undermining that mission.

12. OIRA should consider formulating a guidance document that highlights any considerations common to agency retrospective analyses generally.

Promoting Outside Input

13. Regulated parties, non-governmental organizations, academics, and other outside entities or individuals may possess valuable information concerning both the impact of individual regulations and the cumulative impact of a body of regulations issued by multiple agencies to which individual agencies might not otherwise have access. Agencies should leverage outside expertise both in reassessing existing regulations and devising retrospective review plans for new regulations. In so doing, agencies should be mindful of the potential applicability of the Paperwork Reduction Act, and agencies and OMB should utilize flexibilities within the Act and OMB's implementing regulations (*e.g.,* a streamlined comment period for collections associated with proposed rules) where permissible and appropriate. Agencies should also consider using social media, as appropriate, to learn about actual experience under the relevant regulation(s).

14. Agencies should disclose relevant data concerning their retrospective analyses of existing regulations on ''regulations.gov,'' their Open Government Web pages, and/or other publicly available Web sites. In so doing, to the extent appropriate, agencies should organize the data in ways that allow private parties to recreate the agency's work and to run additional analyses concerning existing rules' effectiveness. Agencies should encourage private parties to submit information and analyses and should integrate relevant information into their retrospective reviews.

Ensuring Adequate Resources

15. Agencies and OMB should consider agencies' retrospective review needs and activities when developing and evaluating agency budget requests. To the extent that agencies require additional resources to conduct appropriately searching retrospective reviews, Congress should fund agencies as necessary.

Administrative Conference Recommendation 2014–6

Petitions for Rulemaking

Adopted December 5, 2014

Under the Administrative Procedure Act (APA), federal agencies are required to ''give . . . interested person[s] the right to petition for the issuance, amendment, or repeal of a rule.'' [1] The statute generally does not establish procedures agencies must observe in connection with petitions for rulemaking. It does, however, require agencies to respond to petitions for rulemaking ''within a reasonable time,'' [2] and to give petitioners ''prompt notice'' when a petition is denied in whole or in part, along with ''a brief statement of the grounds for denial.'' [3] Beyond the APA's general right to petition, Congress has occasionally granted more specific rights to petition under individual statutes, such as the Clean Air Act.[4] Although agency denials of petitions for rulemaking are subject to judicial review, the ''courts have properly limited their scope of review in this context.'' [5]

The Administrative Conference has previously recommended basic procedures to help agencies meet the APA's minimum requirements and respond promptly to petitions for rulemaking.[6] An Administrative Conference study of agency procedures and practices with respect to petitions for rulemaking has revealed, however, that further improvement is warranted.[7] Nearly thirty years after the Administrative Conference first examined this issue, few agencies have in place official procedures for accepting, processing, and responding to petitions for rulemaking.[8] How petitions are received and treated varies across—and even within—agencies. In some cases, agency personnel do not even know what their agency's procedures are for handling petitions. Although the petitioning process can be a tool for enhancing public engagement in rulemaking, in practice most

[1] 5 U.S.C. 553(e). This provision ensures that the people's right to petition the government, which is protected by the First Amendment, *see* U.S. Const. amend. I, is also an important part of the rulemaking process. Although certain matters are exempt from the requirements of 5 U.S.C. 553, *see* U.S.C. 553(a), the Administrative Conference has previously taken the position that public participation in agency rulemaking on these matters, including through petitions for rulemaking, may be beneficial. *See* Administrative Conference of the United States, Recommendation 86–6, *Petitions for Rulemaking,* 51 FR 46988 n.2 (Dec. 30, 1986).

[2] 5 U.S.C. 555(b).

[3] 5 U.S.C. 555(e). The APA exempts agencies from the requirement of providing a ''brief statement of the grounds for denial'' when it is ''affirming a prior denial or when the denial is self-explanatory.'' *Id.*

[4] *See, e.g.,* 42 U.S.C. 7671a(c)(3), 7671e(b), 7671j(e). Statutory petition provisions such as these may impose additional procedural requirements beyond those contained in the APA or identify substantive requirements that must be met before the agency can act.

[5] Administrative Conference of the United States, Recommendation 95–3, *Review of Existing Agency Regulations,* 60 FR 43,109 (Aug. 18, 1995). In general, courts do not require agencies to respond to every individual issue raised in a petition (let alone every issue raised in comments on petitions), so long as the administrative record demonstrates a reasoned response on the whole. *Cf. Nader* v. *FAA,* 440 F.2d 292, 294 (D.C. Cir. 1971); WildEarth Guardians v. Salazar, 741 F. Supp. 2d 89, 104 n.21 (D.D.C. 2012). In *Connecticut* v. *Daley,* a district court raised the ''question whether the [agency] must respond in detail to each and every comment received, or if [it] is only required to respond to what was raised in the actual petition for rule making.'' 53 F. Supp. 2d 147, 170 (D. Conn. 1999). Although the court did not resolve that question, it noted that 5 U.S.C. 555(e) requires agencies to briefly explain only why a ''*petition*'' was denied, impliedly not extending the required response to comments on petitions (citing WWHT, Inc. v. FCC, 656 F.2d 807, 813 (D.C. Cir. 1981) (emphasis added by D. Conn.)).

[6] *See* Administrative Conference of the United States, Recommendation 86–6, *Petitions for Rulemaking,* 51 FR 46988 (Dec. 30, 1986); *see also* Administrative Conference of the United States, Recommendation 95–3, ¶ VI(B) (''Agencies should establish deadlines for their responses to petitions; if necessary, the President by executive order or Congress should mandate that petitions be acted upon within a specified time.'').

[7] *See* Jason A. Schwartz & Richard L. Revesz, *Petitions for Rulemaking,* Final Report to the Administrative Conference of the United States (Nov. 5, 2014), *available at http://www.acus.gov/report/petitions-rulemaking-final-report.*

[8] *See id.* at 46; *see also* William V. Luneburg, *Petitions for Rulemaking: Federal Agency Practice and Recommendations for Improvement,* 1986 ACUS 493, 510 (1986) (observing that, with respect to agency procedures governing petitions for rulemaking, ''[s]ome have none; others largely mirror, without elaborating much on, statutory procedures; and still others have adopted rather detailed requirements . . . going considerably beyond the procedures expressly mandated by statute'').

petitions for rulemaking are filed by sophisticated stakeholders and not by other interested members of the public. Some petitioners report that it can be difficult to learn the status of a previously filed petition, agency communication throughout the process can be poor, response times can be slow, and agency explanations for denials can be minimal and predominantly non-substantive.[9]

Although the right to petition can be important and valuable, making the process work well requires a difficult balancing of competing interests. On the one hand, the APA grants to the public the right to petition for rulemaking and requires agencies to provide a decision on the merits within a reasonable period of time. To be sure, agencies often receive suggestions for new regulations and feedback regarding needed changes to existing regulations via informal channels, such as through meetings with regulated parties and stakeholders or interactions during inspections or other enforcement activities. Petitions provide another important avenue for such input—one that in theory is more broadly accessible to interested persons who do not regularly interact with agency personnel. Nonetheless, petitions for rulemaking may adversely affect an agency's ability to control its agenda and make considered, holistic judgments about regulatory priorities, particularly in the face of limited resources. And thoughtfully evaluating petitions and defending denials on judicial review may consume already scarce agency resources.

Greater transparency, improved communication between agencies and petitioners, and more prompt and explanatory petition responses may help to balance these competing interests.[10] Agencies should educate the public about how petitions fit with the other (often more informal) mechanisms through which agencies receive feedback from regulated and other interested persons on regulatory priorities and related issues. Petitioners and agency personnel alike would also benefit from greater clarity as to how petitions can be filed, what information should be included to make a petition more useful and easier for the agency to evaluate,[11] whether or when public comment will be invited, and how long it may take to resolve a petition. Better internal coordination may reduce the possibility that a petition will be forgotten or will not reach the appropriate agency office for decision. Encouraging communication between prospective or current petitioners and the agency can provide an efficient way to improve the quality of petitions and the overall experience for all participants in the process. Readily available information on the status of pending petitions and more prompt disposition of petitions may improve understanding between the agency and the public and reduce the likelihood of litigation.

This recommendation seeks to ensure that the public's right to petition is a meaningful one, while still respecting the need for agencies to retain decisional autonomy. Building upon the Administrative Conference's previous work, it provides more guidance to agencies, identifying best practices that may make the petitioning process more useful for agencies, petitioners, and other members of the public. Moreover, electronic rulemaking dockets and agency Web sites provide new opportunities for agencies to achieve these goals in a cost-effective manner.[12] This recommendation should help agencies reevaluate and revise their existing policies and procedures to make the petitioning process work better for all.

Recommendation

Agency Policy on Petitions for Rulemaking

1. Each agency that has rulemaking authority should have procedures, embodied in a written and publicly available policy statement or procedural rule, explaining how the agency receives, processes, and responds to petitions for rulemaking filed under the Administrative Procedure Act.

(a) If an agency also has more specific regulations that govern petitions filed under other statutes or that apply to specific sub-agencies, the agency's procedures should cross-reference those regulations.

(b) If an agency rarely receives petitions for rulemaking, its procedures may simply designate an agency contact who can provide guidance to prospective petitioners.

(c) The procedures should explain how petitions relate to the various other options available to members of the public for informally engaging with agency personnel on the need to issue, amend, or repeal rules.

2. The procedures should indicate how the agency will coordinate the consideration of petitions with other processes and activities used to determine agency priorities, such as the Unified Agenda and retrospective review of existing rules.

3. The procedures should explain what type of data, argumentation, and other information make a petition more useful and easier for the agency to evaluate. The procedures should also identify any information that is statutorily required for the agency to act on a petition.

Receiving and Processing Petitions

4. Agencies should accept the electronic submission of petitions, via email or through Regulations.gov (such as by maintaining an open docket for the submission of petitions for rulemaking) or their existing online docketing system.

5. Agencies should designate a particular person or office to receive and distribute all petitions for rulemaking to ensure that each petition for rulemaking is expeditiously directed to the appropriate agency personnel for consideration and disposition. This designation may be especially important for agencies that have multiple regions or offices.

Communicating With Petitioners

6. Agencies should encourage and facilitate communication between agency personnel and petitioners, both prior to submission and while petitions are pending disposition. For example, agencies should consider asking petitioners to clarify requests or submit additional information that will make the petition easier to evaluate. Agencies should consider also alerting petitioners to recent developments that may warrant a petition's modification or withdrawal.

7. Agencies should provide a way for petitioners and other interested persons to learn the status of previously filed petitions. Agencies should:

(a) Use online dockets to allow the public to monitor the status of petitions; and

(b) Designate a single point of contact authorized to provide information about the status of petitions.

Soliciting Public Comment on Petitions

8. Agencies should consider inviting public comment on petitions for rulemaking by either:

(a) Soliciting public comment on all petitions for rulemaking; or

(b) Deciding, on a case-by-case basis, whether to solicit public comment on petitions for rulemaking. Inviting public comment may be particularly appropriate when:

(i) A petition addresses a question of policy or of general interest; or

(ii) Evaluating a petition's merits may require the agency to consider information the agency does not have, or the agency believes that the information provided by the petitioner may be in dispute or is incomplete.

9. If an agency anticipates that it will consider but not respond to all comments on a petition for rulemaking, it should say so in its request for comments.

Responding to Petitions for Rulemaking

10. Agencies should docket each decision with the petition to which it responds.

11. If an agency denies a petition, where feasible and appropriate, it should provide a reasoned explanation beyond a brief statement of the grounds for denial. Agencies should not reflexively cite only resource constraints or competing priorities.

12. Agencies must respond to petitions within a reasonable time. To that end, each agency should:

(a) Adopt in its procedures an expectation that it will respond to all petitions for rulemaking within a stated period (*e.g.,* within 6, 12, or 18 months of submission); and/or

(b) Establish and make publicly available an individual target timeline for responding to that petition.

13. If an agency is unable to respond to a petition by the target timeline it has established, it should provide the petitioner and the public with a brief explanation for the delay, along with a reasonable new target timeline. The explanation may include a request for new or additional information if the agency believes it would benefit from that or the facts or circumstances relevant to the petition may have changed while the petition was pending.

[9] *See* Schwartz & Revesz, *supra* note 7, at 40–64.

[10] *See generally id.*

[11] This could be similar to the information some agencies provide on their Web sites to help the public understand the characteristics of an effective rulemaking comment.

[12] *See, e.g.,* Administrative Conference of the United States, Recommendation 2011–8, *Agency Innovations in E-Rulemaking,* 77 FR 2257, 2264–65 (Jan. 17, 2012).

Providing Information on Petitions for Rulemaking

14. Agencies should maintain a summary log or report listing all petitions, the date each was received, and the date of disposition or target timeline for disposition (where necessary, this should include the brief explanation for any delay in disposition and the reasonable new target timeline). The log or report should be described in the agency's procedures (*see* paragraph 1) and made publicly available on the agency's Web site. It should be updated at least semi-annually. Agencies should create and maintain the summary log or report beginning on the date of this recommendation and should also include or otherwise publicly provide, to the extent feasible, historic information about petitions for rulemaking that have been resolved.

15. The Office of Information and Regulatory Affairs should request that agencies include in their annual regulatory plan information on petitions for rulemaking that have been resolved during that year or are still pending.

Using Electronic Tools To Improve the Petitioning Process

16. Agencies should use available online platforms, including their Web sites and Regulations.gov, to implement this recommendation as effectively and efficiently as possible, including by informing the public about the petitioning process, facilitating the submission of petitions, inviting public comment, providing status updates, improving the accessibility of agency decisions on petitions, and annually providing information on petitions for rulemaking that have been resolved or are still pending.

Administrative Conference Recommendation 2014–7

Best Practices for Using Video Teleconferencing for Hearings

Adopted December 5, 2014

Agencies conduct thousands of adjudicative hearings every day, but the format of the hearing, whether face-to-face or by video, has not been analyzed in any systematic way. Some agencies have provided hearings by video teleconferencing technology (VTC) for decades and have robust VTC programs. These programs strive consistently to provide the best hearing experience, even as technology changes. Other agencies have been reluctant to depart from traditional formats. Some are skeptical that hearings may be conducted as effectively via VTC as they are in person. Others are uncertain about how to implement VTC hearings. But all could benefit from an impartial look at the available technologies for conducting adjudications.

The varied agency experiences and concerns reflect the tension between long-established values and technological innovations. Adjudicative hearings must be conducted in a manner consistent with due process and the core values of fairness, efficiency, and participant satisfaction reflected in cases like *Goldberg* v. *Kelly*[1] and *Mathews* v. *Eldridge.*[2] At the same time, agencies that have explored the use of technological alternatives have achieved benefits in the effective use of decisionmaking resources and reduction in travel expenses.[3] Upholding core values and making the best use of technology—both in hearings and related proceedings such as initial appearances, pre-hearing conferences, and meetings—is the challenge this recommendation seeks to meet.[4]

In 2011, the Administrative Conference adopted Recommendation 2011–4, *Agency Use of Video Hearings: Best Practices and Possibilities for Expansion*.[5] Recommendation 2011–4 had two main purposes. First, it identified factors for agencies—especially agencies with high volume caseloads—to consider as they determined whether to conduct VTC hearings.[6] Second, it offered several best practices agencies should employ when using VTC hearings.[7] The recommendation concluded by encouraging agencies that have decided to conduct VTC hearings to ''[c]onsult the staff of the Administrative Conference of the United States . . . for best practices, guidance, advice, and the possibilities for shared resources and collaboration.'' [8]

This recommendation builds on Recommendation 2011–4 by providing practical guidance regarding how best to conduct VTC hearings. The Administrative Conference is committed to the principles of fairness, efficiency, and participant satisfaction in the conduct of hearings. When VTC is used, it should be used in a manner that promotes these principles, which form the cornerstones of adjudicative legitimacy.[9] The Conference recognizes that VTC is not suitable for every kind of hearing, but believes greater familiarity with existing agency practices and awareness of the improvements in technology will encourage broader use of such technology.[10] This recommendation aims to ensure that, when agencies choose to offer VTC hearings, they are able to provide a participant experience that meets or even exceeds the in-person hearing experience.[11]

Recommendation

Foundational Factors

1. Agencies should consider the various physical and logistical characteristics of their hearings, including the layout of the hearing room(s) and the number and location(s) of hearing participants (*i.e.,* judge, parties, representatives, and witnesses) and other attendees, in order to determine the kind of video teleconferencing (VTC) system to use. These general principles should guide agencies' consideration:

(a) Video screens should be large enough to ensure adequate viewing of all participants;

(b) Camera images should replicate the in-person hearing experience, including participants' ability to make eye contact with other participants and see the entire hearing room(s). If interpreters are involved, they should be able to see and hear the participants clearly;

(c) Microphones should be provided for each participant who will be speaking during the hearing;

(d) The speaker system should be sufficient to allow all participants to hear the person speaking. If a participant has a hearing impairment, a system that complies with the Americans with Disabilities Act and other applicable laws should be used to connect to the VTC system;

(e) The record should be adequately captured, either by ensuring that the audio system connects with a recording system, or by ensuring that the court reporter can clearly see and hear the proceeding;

(f) Sufficient bandwidth should be provided so that the video image and sound are clear and uninterrupted; and

(g) Each piece of equipment should be installed, mounted, and secured so that it is protected and does not create a hazardous environment for participants or staff.

2. Agencies should ensure that the hearing room conditions allow participants to see, be

[1] 397 U.S. 254 (1970).

[2] 424 U.S. 319 (1976); *see also infra* note 9.

[3] In fact, agencies have been directed to increase efficiency through their use of technology. *See* Exec. Order No. 13,589, 76 FR 70861 (Nov. 15, 2011) (directing agencies to ''devise strategic alternatives to Government travel, including . . . technological alternatives, such as . . . video conferencing'' and to ''assess current device inventories and usage, and establish controls, to ensure that they are not paying for unused or underutilized information technology (IT) equipment, installed software, or services'').

[4] While this recommendation refers primarily to adjudication, it may apply to other proceedings as well.

[5] *See* 76 FR 48795 (Aug. 9, 2011), *available at http://www.acus.gov/recommendation/agency-use-video-hearings-best-practices-and-possibilities-expansion*.

[6] Such factors include whether (1) the agency's statute permits use of VTC; (2) the agency's proceedings are conducive to VTC; (3) VTC may be used without affecting case outcomes; (4) the agency's budget allows adequate investment in VTC; (5) the use of VTC would result in cost savings; (6) the use of VTC would result in a reduction in wait time; (7) the participants (*e.g.,* judges, parties, representatives, witnesses) would find VTC beneficial; (8) the agencies' facilities and administration would be able to support VTC hearings; and (9) the use of VTC would not adversely affect either representation or communication. *See id.*

[7] Best practices include (1) offering VTC on a voluntary basis; (2) ensuring that the use of VTC is outcome-neutral and meets the needs of users; (3) soliciting feedback from participants; (4) implementing VTC via a pilot program and evaluating that program before establishing it more broadly; and (5) providing structured training and ensuring available IT support staff. *Id.*

[8] *Id.*

[9] *See* EF Int'l Language Schools, Inc., 2014 N.L.R.B. 708 (2014) (admin. law judge recommended decision) (finding ''that the safeguards utilized at hearing [to take witness testimony by VTC] amply ensured that due process was not denied to'' the party).

[10] For greater detail about how to implement VTC hearings, see Center for Legal and Court Technology, *Best Practices for Using Video for Hearings and Related Proceedings* (Nov. 6, 2014), *available at http://www.acus.gov/report/best-practices-using-video-teleconferencing-final-report*.

[11] This recommendation does not take a position on when parties should be entitled to, or may request, an in-person hearing.

seen by, and hear other participants, and to see written documents and screens, as well as, or better than, if all of the participants were together in person. These general principles should guide agencies' consideration in creating the best hearing room conditions:

(a) Lighting should be placed in a way to create well-dispersed, horizontal, ambient light throughout all rooms used in the proceeding;

(b) Noise transference should be kept to a minimum by:

(i) Locating hearing rooms in the inner area of the office and away from any noise or vibration-producing elements (*e.g.,* elevator shafts, mechanical rooms, plumbing, and high-traffic corridors); and

(ii) Installing solid doors with door sweeps, walls that run from floor to ceiling, and sound absorption panels on the walls.

(c) Room décor, including colors and finishes of walls and furniture, should allow for the camera(s) to easily capture the image(s).

3. Agencies should retain technical staff to support VTC operators and maintain equipment.

Training

4. Agencies should provide training for agency staff, especially judges, who will operate the VTC equipment during the hearing. Agencies should also provide a reference chart or ''cheat sheet'' to keep with each VTC system that provides basic system operation directions that operators can easily reference, as well as a phone number (or other rapid contact information) for reaching technical staff.

5. Agencies should provide advanced training for technical support staff to ensure they are equipped to maintain the VTC equipment and provide support to operators, including during a proceeding if a problem arises.

Financial Considerations

6. The capabilities and costs of VTC systems vary widely. Before purchasing or updating their VTC systems, agencies should first consider their hearing needs (*e.g.,* the needs of hearings conducted by judges at their desks with a single party will be different than the needs of hearings conducted in full-sized federal courtrooms with multiple participants and attendees present at several locations) both now and in the future (*e.g.,* the bandwidth needed today may be different than the bandwidth needed tomorrow).

7. Once agencies have identified their hearing needs, they should consider the costs and benefits of implementing, maintaining, and updating their VTC systems to suit those needs.

(a) Costs to be considered include those associated with purchasing, installing, and maintaining the VTC system; creating and maintaining the conditions necessary to allow participants to see and hear each other clearly; and providing training to staff.

(b) Benefits to be considered include better access to justice by increased accessibility to hearings, more efficient use of time for judges and staff, reduced travel costs and delays, and backlog reductions.

Procedural Practices

8. Judges should consider how to establish and maintain control of the hearing room, such as by wearing robes as a symbol of authority, appearing on the screen before the other participants enter the room(s), requiring parties and representatives to use hand signals to indicate that they would like to speak, and reminding representatives that they are officers of the court.

9. Agencies should install VTC equipment so that judges can control the camera at the other location(s), if possible.

10. Agency staff should ensure that the hearing will run as smoothly as possible by removing any obstacles blocking lines-of-sight between the camera and participants and testing the audio on a regular basis.

Fairness and Satisfaction

11. Agencies should periodically assess their VTC hearings program to ensure that the use of VTC produces outcomes that are comparable to those achieved during in-person hearings.

12. Agencies should maintain open lines of communication with representatives in order to receive feedback about the use of VTC. Post-hearing surveys or other appropriate methods should be used to collect information about the experience and satisfaction of participants.

Collaboration Among Agencies

13. Agencies should consider sharing VTC facilities and expertise with each other in order to reduce costs and increase efficiency, while maintaining a fair and satisfying hearing experience.

14. Agencies that conduct hearings should work with the General Services Administration (GSA) in procuring and planning facilities that will best accommodate the needs of VTC hearings.

Development of a Video Teleconferencing Hearings Handbook

15. The Office of the Chairman of the Administrative Conference of the United States should create a handbook on the use of VTC in hearings and related proceedings that will be updated from time to time as technology changes. The handbook should reflect consultation with GSA and other agencies with VTC hearings expertise. It should be made publicly accessible online to agencies, and include specific guidance regarding equipment, conditions, training that meets industry standards, and methods for collecting feedback from participants.

[FR Doc. 2014–29546 Filed 12–17–14; 8:45 am]

BILLING CODE 6110–01–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Announcement of Grant Application Deadlines and Funding Levels

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of solicitation of applications (NOSA).

SUMMARY: The Rural Utilities Service, a Rural Development agency of the United States Department of Agriculture (USDA), herein referred to as RUS or the Agency, announces its Community Connect Grant Program application window for Fiscal Year (FY) 2015. This notice is being issued prior to passage of a final appropriations act to allow potential applicants time to submit proposals and give the Agency time to process applications within the current fiscal year. RUS will publish on its Web site the amount of funding received in any continuing resolution or the final appropriations act, if any. Expenses incurred in developing applications will be at the applicant's risk.

In addition to announcing the application window, RUS announces the minimum and maximum amounts for Community Connect grants applicable for the fiscal year. The Community Connect Grant Program regulations can be found at 7 CFR 1739, subpart A.

DATES: You may submit completed applications for grants on paper or electronically according to the following deadlines:

- Paper copies must carry proof of shipping *no later* than February 17, 2015 to be eligible for FY 2015 grant funding. Late applications are not eligible for FY 2015 grant funding.
- Electronic copies must be received by February 17, 2015 to be eligible for FY 2015 grant funding. Late applications are not eligible for FY 2015 grant funding.

ADDRESSES: You may obtain application guides and materials for the Community Connect Grant Program via the Internet at the following Web site: *http://www.rurdev.usda.gov/utp_commconnect.html.* You may also request application guides and materials from RUS by contacting the appropriate individual listed in section VII of the **SUPPLEMENTARY INFORMATION** section of this notice.

Submit completed paper applications for grants to the Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 2808, STOP 1597, Washington, DC 20250–1597. Applications should be marked ''Attention: Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service.''

Submit electronic grant applications at *http://www.grants.gov* (Grants.gov), following the instructions you find on that Web site.

FOR FURTHER INFORMATION CONTACT: Shawn Arner, Deputy Assistant Administrator, Loan Origination and

Approval Division, Rural Utilities Service, U.S. Department of Agriculture, telephone: (202) 720–0800, fax: (202) 205–2921.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service (RUS).

Funding Opportunity Title: Community Connect Grant Program.

Announcement Type: Initial announcement.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.863.

Dates: You may submit completed applications for grants on paper or electronically according to the following deadlines:

- Paper copies must carry proof of shipping no later than February 17, 2015, to be eligible for FY 2015 grant funding. Late applications are not eligible for FY 2015 grant funding.
- Electronic copies must be received by February 17, 2015, to be eligible for FY 2015 grant funding. Late applications are not eligible for FY 2015 grant funding.

Items in Supplementary Information

I. Funding Opportunity

RUS improves the quality of life in rural America by providing investment capital, in the form of loans and grants, for the deployment of rural telecommunications infrastructure. Financial assistance is provided to rural utilities; municipalities; commercial corporations; limited liability companies; public utility districts; Indian tribes; and cooperative, nonprofit, limited-dividend, or mutual associations. In order to achieve the goal of increasing economic opportunity in rural America, the Agency finances infrastructure that enables access to a seamless, nation-wide telecommunications network. With access to the same advanced telecommunications networks of its urban counterparts, especially broadband networks designed to accommodate distance learning, telework and telemedicine, rural America will see improving educational opportunities, health care, economies, safety and security, and ultimately higher employment. Of particular concern to the Agency are communities where broadband service is not available and where population densities are such that the cost of deployment to them is high and buildout of infrastructure is unlikely.

The provision of broadband service is vital to the economic development, education, health, and safety of rural Americans. The purpose of the Community Connect Grant Program is to provide financial assistance in the form of grants to eligible applicants that will provide currently unserved areas, on a ''community-oriented connectivity'' basis, with broadband service that fosters economic growth and delivers enhanced educational, health care, and public safety services. RUS will give priority to rural areas that have the greatest need for broadband services, based on the criteria contained herein.

Grant authority will be used for the deployment of broadband service to extremely rural, lower-income communities on a ''community-oriented connectivity'' basis. The ''community-oriented connectivity'' concept will stimulate practical, everyday uses and applications of broadband facilities by cultivating the deployment of new broadband services that improve economic development and provide enhanced educational and health care opportunities in rural areas. Such an approach will also give rural communities the opportunity to benefit from the advanced technologies that are necessary to achieve these goals. Please see 7 CFR part 1739, subpart A, for specifics.

This notice has been formatted to conform to a policy directive issued by the Office of Federal Financial Management (OFFM) of the Office of Management and Budget (OMB), published in the **Federal Register** on June 23, 2003. This Notice does not change the Community Connect Grant Program regulation (7 CFR 1739, subpart A).

The definitions applicable to this Notice are published at 7 CFR 1739.3.

The Agency will review, evaluate, and score applications received in response to this Notice based on the provisions found in 7 CFR 1739, subpart A, and as indicated in this notice.

II. Award Information

A. Available Funds

1. General. Under 7 CFR 1739.2, the Administrator has established a minimum grant amount of $100,000 and a maximum grant amount of $3,000,000 for FY 2015.

2. Assistance instrument. RUS will execute grant documents appropriate to the project prior to any advance of funds with successful applicants.

B. Community Connect grants cannot be renewed.

Award documents specify the term of each award.

III. Eligibility Information

A. Who is eligible for a Community Connect grant? (See 7 CFR 1739.10.)

1. Only entities legally organized as one of the following are eligible for Community Connect Grant Program financial assistance:

a. An incorporated organization,

b. An Indian tribe or tribal organization, as defined in *25 U.S.C. 450b (e),*

c. A state or local unit of government, or

d. A cooperative, private corporation or limited liability company organized on a for-profit or not-for-profit basis.

2. An applicant must have the legal capacity and authority to own and operate the broadband facilities as proposed in their application, to enter into contracts and to otherwise comply with applicable federal statutes and regulations.

3. An applicant must have an active registration with current information in the System for Award Management (SAM) (previously the Central Contractor Registry (CCR)) at *https://www.sam.gov* and have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number.

B. Who is not eligible for Community Connect grants?

Individuals are not eligible for Community Connect Grant Program financial assistance directly.

C. What are the basic eligibility requirements for a project?

1. General. The regulation for the Community Connect Grant Program requires that certain definitions affecting eligibility be revised and published from time–to-time by the Agency in the **Federal Register**. For the purpose of this regulation, the Agency shall use the following definitions: ''Broadband service'' and ''Broadband Grant Speed.'' Until otherwise revised in the **Federal Register**, for applications

in FY 2015, to qualify as Broadband Service, the minimum rate of data transmission shall be three megabits per second (download plus upload speeds)for both fixed and mobile service and the Broadband Grant Speed will be a minimum bandwidth of five megabits per second (download plus upload speeds) for both fixed and mobile service to the customer.

2. Required matching contributions. Please see 7 CFR 1739.14 for the requirement. Grant applicants must demonstrate a matching contribution, in cash, of at least fifteen (15) percent of the total amount of financial assistance requested. Matching contributions must be used to support the broadband operations funded under the Community Connect Grant Program.

3. To be eligible for a grant, the Project must (see 7 CFR 1739.11):

a. Serve a Proposed Funded Service Area where Broadband Service does not currently exist, to be verified by RUS prior to the award of the grant;

b. Offer service at the Broadband Grant Speed, free of all charges for at least 2 years, to all Critical Community Facilities located within the proposed Service Area;

c. Offer service at the Broadband Grant Speed to all residential and business customers within the Proposed Funded Service Area; and

d. Provide a Community Center with at least two (2) Computer Access Points and wireless access at the Broadband Grant Speed available, free of charge, to all users for at least 2 years.

e. Not overlap with the Service area of current RUS borrowers and grantees.

4. Other requirements:

a. DUNS numbers and SAM registration: Applicants must have a Dun and Bradstreet DUNS number and be registered in System Awards Management (SAM) at *https://www.sam.gov* prior to submitting an electronic or paper application. The DUNS number and SAM requirements are contained in 2 CFR part 25. SAM is the repository for standard information about applicants and recipients.

b. DUNS Number: As required by the OMB, all applicants for grants must supply a Dun and Bradstreet DUNS number when applying. The Standard Form 424 (SF–424) contains a field for you to use when supplying your DUNS number. Obtaining a DUNS number costs nothing and requires a short telephone call to Dun and Bradstreet. Please see *http://www.grants.gov/applicants/org_step1.jsp* for more information on how to obtain a DUNS number or how to verify your organization's number.

c. System for Award Management (SAM): In accordance with 2 CFR part 25, applicants, whether applying electronically or by paper, must be registered in SAM prior to submitting an application. Applicants may register for the SAM at *https://www.sam.gov.* The SAM registration must remain active, with current information, at all times during which an entity has an application under consideration by an agency or has an active Federal Award. To remain registered in the SAM database after the initial registration, the applicant is required to review and update on an annual basis from the date of initial registration or subsequent updates of its information in the SAM database to ensure it is current, accurate and complete.

C. Discussion of completed application items

See paragraph IV.B of this notice for a discussion of the items that make up a completed application. Refer to 7 CFR 1739.15 for completed grant application items.

IV. Application and Submission Information

A. Where To Get Application Information

The application guide, copies of necessary forms and samples, and the Community Connect Grant Program regulation are available from these sources:

1. The Internet: *http://www.rurdev.usda.gov/utp_commconnect.html.*

2. The Rural Utilities Service, Loan Origination and Approval Division, for paper copies of these materials: (202) 720–0800.

B. What constitutes a completed application?

1. Detailed information on each item required can be found in the Community Connect Grant Program regulation and the Community Connect Grant Program application guide. Applicants are strongly encouraged to read and apply both the regulation and the application guide. This Notice does not change the requirements for a completed application for any form of Community Connect Grant Program financial assistance specified in the Community Connect Grant Program regulation. The Community Connect Grant Program regulation and the application guide provide specific guidance on each of the items listed and the Community Connect Grant Program application guide provides all necessary forms and sample worksheets.

2. Applications should be prepared in conformance with the provisions in 7 CFR 1739, subpart A, and applicable USDA regulations including 7 CFR parts 3015, 3016, and 3019. Applicants must use the RUS Application Guide for this program containing instructions and all necessary forms, as well as other important information, in preparing their application. Completed applications must include the following:

a. *An Application for Federal Assistance.* A completed Standard Form (SF) 424.

b. *An executive summary of the Project.* The applicant must provide RUS with a general project overview.

c. *Scoring criteria documentation.* Each grant applicant must address and provide documentation on how it meets each of the scoring criteria detailed in 7 CFR 1739.17.

d. *System design.* The applicant must submit a system design, including, narrative specifics of the proposal, associated costs, maps, engineering design studies, technical specifications and system capabilities, etc.

e. *Service area demographics.* The applicant must provide a map of the Proposed Funded Service Area using the RUS Mapping Tool.

f. *Scope of work.* The scope of work must include specific activities and services to be performed under the proposal, who will carry out the activities and services, specific time-frames for completion, and a budget for all capital and administrative expenditures reflecting the line item costs for all grant purposes, the matching contribution, and other sources of funds necessary to complete the project.

g. *Community-Oriented Connectivity Plan.* The applicant must provide a detailed Community-Oriented Connectivity Plan.

h. *Financial information and sustainability.* The applicant must provide financial statements and information and a narrative description demonstrating the sustainability of the Project.

i. *A statement of experience.* The applicant must provide a written narrative describing its demonstrated capability and experience, if any, in operating a broadband telecommunications system.

j. *Evidence of legal authority and existence.* The applicant must provide evidence of its legal existence and authority to enter into a grant agreement with RUS and to perform the activities proposed under the grant application.

k. *Additional Funding.* If the Project requires additional funding from other sources in addition to the RUS grant, the

applicant must provide evidence that funding agreements have been obtained to ensure completion of the Project.

l. *Federal Compliance.* The applicant must provide evidence of compliance with other federal statutes and regulations, including, but not limited to the following:

(i) 7 CFR part 15, subpart A—Nondiscrimination in Federally Assisted Programs of the Department of Agriculture—Effectuation of Title VI of the Civil Rights Act of 1964.

(ii) 7 CFR part 3015—Uniform Federal Assistance Regulations.

(iii) 2 CFR part 180—OMB Guidelines to Agencies on Government-wide Debarment and Suspension (Nonprocurement)

(iv) 2 CFR part 417—Nonprocurement Debarment and Suspension.

(v) 7 CFR part 3018—New Restrictions on Lobbying.

(vi) 2 CFR part 421—Government-wide Requirements for Drug-Free Workplace (Financial Assistance).

(vii) Certification regarding Architectural Barriers.

(viii) Certification regarding Flood Hazard Precautions.

(ix) An environmental report/questionnaire, in accordance with 7 CFR 1794.

(x) A certification that grant funds will not be used to duplicate lines, facilities, or systems providing Broadband Service.

(xi) Federal Obligation Certification on Delinquent Debt.

C. How many copies of an application are required?

1. Applications submitted on paper: Submit the original paper application and a copy in electronic format to RUS.

2. Applications submitted through Grants.gov: The additional paper copies are not necessary if you submit the application electronically through Grants.gov.

D. How and Where To Submit an Application

Grant applications may be submitted on paper or through Grants.gov.

1. Submitting applications on paper.

a. Address paper applications for grants to the Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 2808, STOP 1597, Washington, DC 20250–1597. Applications should be marked ''Attention: Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service.''

b. Paper applications must show proof of mailing or shipping consisting of one of the following:

(i) A legibly dated U.S. Postal Service (USPS) postmark;

(ii) A legible mail receipt with the date of mailing stamped by the USPS; or

(iii) A dated shipping label, invoice, or receipt from a commercial carrier.

c. Due to screening procedures at the Department of Agriculture, packages arriving via the USPS are irradiated, which can damage the contents. RUS encourages applicants to consider the impact of this procedure in selecting their application delivery method.

2. Applications submitted through Grants.gov.

(a) Applicants may file an electronic application at *http://www.grants.gov.* Applications will not be accepted via facsimile machine transmission or electronic mail. Grants.gov contains full instructions on all required passwords, credentialing, and software. Follow the instructions at Grants.gov for registering and submitting an electronic application. If a system problem or technical difficulty occurs with an electronic application, please use the customer support resources available at the Grants.gov Web site.

(b) First time Grants.gov users should go to the ''Get Started'' tab on the Grants.gov site and carefully read and follow the steps listed. These steps need to be initiated early in the application process to avoid delays in submitting your application online.

E. Deadlines

1. Paper applications must be postmarked and mailed, shipped, or sent overnight no later than February 17, 2015 to be eligible for FY 2015 grant funding. Late applications are not eligible for FY 2015 grant funding.

2. Grant applications submitted through Grants.gov must be received by February 17, 2015 to be eligible for FY 2015 funding. Late applications are not eligible for FY 2015 grant funding.

F. Funding Purposes

1. Eligible grant purposes. Grant funds may be used to finance:

a. The construction, acquisition, or leasing of facilities, including spectrum, land or buildings to deploy service at the Broadband Grant Speed to all participating Critical Community Facilities and all required facilities needed to offer such service to all residential and business customers located within the Proposed Funded Service Area;

b. The improvement, expansion, construction, or acquisition of a Community Center that furnishes free internet access at the Broadband Grant Speed and provision of Computer Access Points. Grant funds provided for such costs shall not exceed the lesser of ten percent (10%) of the grant amount requested or $150,000; and

c. The cost of bandwidth to provide service free of charge at the Broadband Grant Speed to Critical Community Facilities for the first 2 years of operation.

2. Ineligible grant purposes.

a. Grant funds may not be used to finance the duplication of any existing Broadband Service provided by another entity.

b. Operating expenses other than the cost of bandwidth for 2 years to provide service at the Broadband Grant Speed to Critical Community Facilities.

3. Please see 7 CFR 1739.3 for definitions, 7 CFR 1739.12 for eligible grant purposes, and 7 CFR 1739.13 for ineligible grant purposes.

V. Application Review Information

A. Criteria

1. Grant applications are scored competitively and subject to the criteria listed below.

2. Grant application scoring criteria (total possible points: 100). See 7 CFR 1739.17 for the items that will be reviewed during scoring and for scoring criteria.

a. An analysis of the challenges of the following criteria, laid out on a community-wide basis, and how the project proposes to address these issues (up to 50 points): 1. The economic characteristics; 2. Educational Challenges; 3. Health care needs; 4. Public safety issues; and 5. Small Area Income and Poverty Estimates (applications that according to the 2010 census show that at least 20 percent of the population of the counties included in core coverage areas is living in poverty) will receive the maximum score in this category. This emphasis will support Rural Development's mission of improving the quality of life for Rural Americans and commitment to directing resources to those who most need them.

b. The extent of the Project's planning, development, and support by local residents, institutions, and Critical Community Facilities (up to 40 points);

c. The level of experience and past success of operating broadband systems for the management team (up to 10 points); and

d. In making a final selection among and between applications with comparable rankings and geographic distribution, the Administrator may take into consideration the characteristics of the Proposed Funded Service Area (PFSA).

B. Special consideration areas

RUS will offer special consideration to applications that propose to provide broadband service within a trust area or a tribal jurisdictional area. Such applications will be awarded 15 points. The applicant will need to submit evidence indicating that the proposed service area is located in a trust area or a tribal jurisdictional area.

RUS will use one or more of the following resources in determining whether a proposed service area is located in a trust area or tribal jurisdictional area:

(a) Official maps of Federal Indian Reservations based on information compiled by the U.S. Department of the Interior, Bureau of Indian Affairs, and made available to the public;

(b) Title Status Reports issued by the U.S. Department of the Interior, Bureau of Indian Affairs, showing that title to such land is held in trust or is subject to restrictions imposed by the United States;

(c) Trust Asset and Accounting Management System data, maintained by the Department of the Interior, Bureau of Indian Affairs;

(d) Official maps of the Department of Hawaiian Homelands of the State of Hawaii identifying land that has been given the status of Hawaiian home lands under the provisions of section 204 of the Hawaiian Homes Commission Act, 1920;

(e) Official records of the U.S. Department of the Interior, the State of Alaska, or such other documentation of ownership as the RUS may determine to be satisfactory, showing that title is owned by a Regional Corporation or a Village Corporation as such terms are defined in the Alaska Native Claims Settlement Act (43 U.S.C. 1451 *et seq.*); and

(f) Any other evidence submitted by the applicant that is satisfactory to RUS to establish that area where the end-user site is located is a trust area or a tribal jurisdictional area within the meaning of 38 U.S.C. 3765(1).

C. Review Standards

1. All applications for grants must be delivered to RUS at the address and by the date specified in this notice or electronically submitted by the deadline (see also 7 CFR 1739.2) to be eligible for funding. The Agency will review each application for conformance with the provisions of this part. RUS may contact the applicant for additional information or clarification.

2. Incomplete applications as of the deadline for submission will not be considered. If an application is determined to be incomplete, the applicant will be notified in writing and the application will be returned with no further action.

3. Applications conforming with this part will then be evaluated competitively by a panel of Rural Utilities Service employees selected by the Administrator of Rural Utilities Service, and will be awarded points as described in the scoring criteria in 7 CFR 1739.17. Applications will be ranked and grants awarded in rank order until all grant funds are expended.

D. Selection Process

Grant applications are ranked by final score. The Rural Utilities Service selects applications based on those rankings, subject to the availability of funds and consistent with 7 CFR 1739.17.

VI. Award Administration Information

A. Award Notices

The Rural Utilities Service recognizes that each funded project is unique, and therefore may attach conditions to different projects' award documents. RUS generally notifies applicants whose projects are selected for awards by emailing a scanned copy of an award letter. RUS follows the award letter with a grant agreement that contains all the terms and conditions for the grant. An applicant must execute and return the grant agreement, accompanied by any additional items required by the grant agreement.

B. Administrative and National Policy Requirements

The items listed in paragraph IV.B.2.l. of this notice, and the Community Connect Grant Program regulation, application guide and accompanying materials implement the appropriate administrative and national policy requirements.

C. Reporting

1. Performance reporting. All recipients of Community Connect Grant Program financial assistance must provide annual performance activity reports to RUS until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project. See 7 CFR 1739.19.

2. Financial reporting. All recipients of Community Connect Grant Program financial assistance must provide an annual audit, beginning with the first year a portion of the financial assistance is expended. Audits are governed by United States Department of Agriculture audit regulations. See 7 CFR 1739.20.

3. Recipient and Subrecipient Reporting. The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

a. First Tier Sub-Awards of $25,000 or more (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov* no later than the end of the month following the month the obligation was made.

b. The Total Compensation of the Recipient's Executives (5 most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *http://www.sam.gov* by the end of the month following the month in which the award was made.

c. The Total Compensation of the Subrecipient's Executives (5 most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

VII. Agency Contacts

A. Web site: *http://www.rurdev.usda.gov/utp_commconnect.html*. This Web site maintains up-to-date resources and contact information for the Community Connect Grant Program.

B. Phone: (202) 720–0800

C. Fax: (202) 205–2921

D. Main point of contact: Shawn Arner, Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service, U.S. Department of Agriculture.

Dated: December 11, 2014.

Jasper Schneider,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2014–29600 Filed 12–16–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–165–2014]

Foreign-Trade Zone 57—Charlotte, North Carolina Application for Expansion of Subzone 57C DNP Imagingcomm America Corporation Concord, North Carolina

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Charlotte Regional Partnership, Inc., grantee of FTZ 57, requesting the expansion of Subzone 57C, located at the facility of the DNP Imagingcomm America Corporation in Concord, North Carolina. 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 December 10, 2014.

The grantee proposes to expand Subzone 57C to include an additional 12.93 acres (new subzone total acreage = 27.63 acres). The subzone is located at 4541 Enterprise Drive NW., Concord, Cabarrus County, North Carolina. The subzone would be subject to the existing activation limit of FTZ 57. No authorization for production activity has been requested at this time.

In accordance with the FTZ Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is January 26, 2015. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to February 10, 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 Kathleen Boyce at *Kathleen.Boyce@trade.gov* at (202) 482–1346.

Dated: December 10, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–29597 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1955]

Reorganization of Foreign-Trade Zone 203 (Expansion of Service Area) Under Alternative Site Framework Moses Lake, Washington

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Port of Moses Lake Public Corporation, grantee of Foreign-Trade Zone 203, submitted an application to the Board (FTZ Docket B–49–2014, docketed 07/03/2014) for authority to expand the service area of the zone to include Adams County, Washington, as described in the application, adjacent to the Moses Lake, Washington, U.S. Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (79 FR 39365–39366, 07/10/2014, correction 79 FR 41259, 07/15/2014) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 203 to expand the service area under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Signed at Washington, DC, this 4th day of December 2014.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2014–29602 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; Survey of International Air Travelers

AGENCY: International Trade Administration, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before February 17, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Richard Champley or Ron Erdmann, ITA National Travel & Tourism Office (NTTO), 1401 Constitution Ave. NW., Washington, DC 20230, Phone: (202) 482–0140, Fax: (202) 482–2887. Email: *Richard.Champley@trade.gov* or *Ron.Erdmann@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The ''Survey of International Air Travelers'' (Survey) program, administered by the National Travel and Tourism Office (NTTO) of the International Trade Administration provides source data required to (1) estimate international travel and passenger fare exports, imports and the trade balance for the United States, (2) comply with the U.S. Travel Promotion Act of 2009 (Pub. L. 111–145), collect a one percent sample of inbound travelers, analyze and report information to the Corporation for Travel Promotion (CTP), d/b/a Brand USA, and support the National Export Initiative (NEI) to double exports for the country, (3) to comply with the 1961, 1981, and 1996 travel and tourism related acts to collect and publish comprehensive international travel and tourism, statistics and other marketing information, and (4) support the

continuation of the Travel & Tourism Satellite Accounts for the United States, which provide the only spending and employment figures for the industry, and (5) to support the goals of objectives of the President's National Travel & Tourism Strategy.

The Survey program contains the core data that is collected, analyzed and communicated by NTTO with other government agencies, associations and businesses that share the same objective of increasing U.S. international travel exports. The Survey assists NTTO in assessing the economic impact of international travel on state and local economies, providing visitation estimates, key market intelligence, and identifying traveler and trip characteristics. The U.S. Department of Commerce assists travel industry enterprises to increase international travel and passenger fare exports for the country as well as outbound travel on U.S. carriers. The Survey program provides the only available estimates of nonresident visitation to the states and cities within the United States, as well as U.S. resident travel abroad.

A new survey instrument (questionnaire) (English version plus its translations into eleven foreign languages) was implemented in 2012. It reflects input from over 70 respondents, including: Travel Industry (airlines, travel associations, destinations, lodging); Consultants; Financial Firms; Educational Institutions; and other U.S. Government Agencies.

The new Survey questionnaire reflects changes in various questions relating to: Trip purpose; Payment methods; Booking/Information sources; additional package components, health care/vaccinations, travel insurance information, additional transportation utilized, Assessment of the Visitor's Experience; and intentions for further travel to the United States; Ethnicity/race. Several questions from the pre-existing 1996 questionnaire were eliminated to further streamline the survey.

II. Method of Collection

The survey instrument/questionnaire (''Survey of International Air Travelers'') continues to be in paper format and is self-administered by the passenger who volunteers to take the survey, either while in the departure gate area or on-board the flight. The flights are selected randomly and this approach is described as 'cluster sampling.' The majority (80%) of the passenger surveys are collected in U.S. airport departure gate areas. About 20% of all the passenger surveys are collected during flight (on-board) post departure (Canada is not part of the program). U.S. and foreign flag airlines that volunteer to participate in the Survey program enable the collection either in U.S. departure gate areas or on-board flights.

NTTO is planning to change the format to electronic or to a more efficient and equally statistically valid process once compelling results have been attained. To date there have been 'e-Survey tests' in partnership with Global Distribution Systems (GDS) and with a major airline in its boarding area. Other tests are planned this year including the goal to leverage personal electronic devices (PED) and Wi-Fi capabilities in the airport and on-board certain flights.

III. Data

OMB Control Number: 0625–0227.

Form Number(s): None.

Type of Review: Regular submission [extension of a current information collection].

Affected Public: Individuals or households.

Estimated Number of Respondents: 300,000 [changed from 99,400 due to mandate of the Travel Promotion Act which requires a 'one percent' sample of overseas arrivals].

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 75,000.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 11, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–29463 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 14–00004]

Export Trade Certificate of Review

ACTION: Notice of Application for an Export Trade Certificate of Review for DFA of California, Application no. 14–00004.

SUMMARY: The Office of Trade and Economic Analysis (''OTEA'') of the International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review (''Certificate''). This notice summarizes the application and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov*.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business

information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Export Trading Company Affairs, International Trade Administration, U.S. Department of Commerce, Room 7025–X, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 14–00004.''

A summary of the current application follows.

Summary of the Application

Applicant: DFA of California, 710 Striker Avenue Sacramento, CA 95834.

Contact: Matthew Krehe, Senior Manager with Gilbert Associates, Inc., (916) 646–6464.

Application No.: 14–00004.

Date Deemed Submitted: December 1, 2014.

Summary: DFA of California (''DFA'') seeks a Certificate of Review to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets.

Export Trade

Products: California Figs, Prunes and Walnuts in processed and unprocessed form. HS codes that best describe these products include, Figs (HS Code 080420), ''Natural Condition'' and Processed Prunes (HS Code 081320), In-shell Walnuts (HS Code 080231), and Shelled Walnuts (HS Code 080232).

Services: All services related to the export of Products.

Technology Rights: All intellectual property rights associated with Products or Services, including, but not limited to: Patents, trademarks, services marks, trade names, copyrights, neighboring (related) rights, trade secrets, know-how, and confidential databases and computer programs.

Export Trade Facilitation Services (as They Relate to the Export of Products): All export trade related facilitation services, including but not limited to: Development of trade strategy; sales, marketing, and distribution; foreign market development; export promotion; and all aspects of foreign sales transactions, including export brokerage, freight forwarding, transportation, insurance, billing, collection, trade documentation, and foreign exchange; customs, duties, and taxes; and inspection and quality control.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of Northern Mariana Islands, and the Territory of the Pacific Islands).

Export Trade Activities and Methods of Operations

To engage in Export Trade in the Export Markets, DFA may exchange and discuss with its Members the following information:

1. With respect to the Export Markets, information about the sales and marketing efforts, activities and opportunities for sales of Products, selling strategies, sales, contract and spot pricing, projected demands, customary terms of sale, and specifications for Products by customers;

2. Information about the price, quality, quantity, source, and delivery dates of Products available from the Members for export;

3. Information about terms and conditions of contracts for sale in the Export Markets to be considered and/or bid on by DFA and its Members;

4. Information about joint bidding or selling arrangements for the Export Markets and allocations of sales resulting from such arrangements among the Members;

5. Information about expenses specific to exporting to and within the Export Markets, including without limitation, transportation, trans- or intermodal shipments, insurance, inland freight to port, port storage, commissions, export sales, documentation, financing, customs, duties, and taxes;

6. Information about U.S. and foreign legislation and regulations, including federal marketing order programs, affecting sales of Products for the Export Markets;

7. Information about DFA's or its Members' export operations, including without limitation, sales and distribution networks established by DFA or its Members in the Export Markets, and prior export sales by Members (including export price information); and

8. Information about export customer credit terms and credit history.

DFA and its Members may prescribe the following conditions for admission of members of DFA as participants in the Export Trade Activities and Methods of Operation and as new Members of the Certificate (within the meaning of 15 CFR 325.2(l)) and termination of Membership:

1. Membership shall be limited to Fig, Prune or Walnut Processors and Packers as defined under ''Definitions.''

2. Membership shall terminate on the occurrence of one of more of the following events:

i. Withdrawal or resignation of the a Member;

ii. Expulsion approved by a majority of all Members for a material violation of DFA's Operating Agreement, after prior written notice to the Member proposed to be expelled and an opportunity of such Member to appear and be heard before a meeting of the Members;

iii. Death or permanent disability of a Member who is an individual or the dissolution of a Member other than an individual; or

iv. The bankruptcy of a Member as provided in DFA's By-Laws.

3. DFA and its Members may establish the following Minimum Qualifications to participate in the DFA of California's Export Committees for Figs, Natural Condition Prunes, Prune Processors, and Walnuts. A participant must be:

i. A DFA Member;

ii. Owner of a commercially viable processing facility;

iii. In good standing with DFA credit terms (Payment net 30); and

iv. Its personal and business conduct must be considered consistent with the highest industry standards as necessary to protect the integrity of the committee.

a. Fig Export Committee: Refer to Minimum Qualifications.

b. Natural Condition Prune Export Committee:

i. In addition to meeting the Minimum Qualifications, participation in this export committee requires the Member to be a packer of natural condition prunes for export.

b. Prune Processor Export Committee:

i. In addition to meeting the Minimum Qualifications, participation in this export committee requires the Member to be a processor of processed prunes for export.

ii. Participation also requires that the Member has the capability to thermally process and pack fruit into a consumer-ready product to a minimum 25% moisture level suitable for end user consumption.

c. Walnut Export Committee: Refer to Minimum Qualifications.

Definition

1. ''Supplier'' means a person who produces, provides, or sells Products, Services, and/or Technology Rights.

2. ''Export Intermediary'' means a person (including a Member) who acts as a distributor, sales representative, sales or marketing agent, or broker, or who provides similar functions, including providing, or arranging the provision of, Export Trade Facilitation Services.

3. ''Processor or Packer'' means a person who processes or packs figs, prunes or walnuts grown in California.

4. ''Member'' means the Members of DFA listed below and any other members of DFA added as Members under the Certificate through amendment of the Certificate.

5. ''Natural Condition Prunes'' means prunes (with pits) in the condition in which they are normally delivered from a dry yard or dehydrator and may include:

a. Prunes which have been washed, but which retain natural condition;

b. Prunes which will permit normal bulk storage without adding a preservative;

c. Prunes which have been size graded;

d. Prunes which may have been processed and re-dried to acceptable natural condition moisture content; and

e. Prunes in which the average moisture content of a lot is 21% or less.

4. ''Processed Prunes'' means prunes which have been thermally processed (*e.g.*treated with hot water or steam) in the course of their preparation for packaging to the extent that their condition no longer meets the definition of ''natural condition.''

The members of DFA of California proposed as Members under the Certificate within the meaning of 15 CFR 325.2(l):

1. Alpine Pacific Nut Company (Hughson, CA)
2. Andersen & Sons Shelling (Vina, CA)
3. Avanti Nut Company, Inc. (Stockton, CA)
4. Berberian Nut Company, LLC (Chico, CA)
5. Carriere Family Farms, Inc. (Glenn, CA)
6. Continente Nut LLC (Oakley, CA)
7. Crain Walnut Shelling, Inc. (Los Molinos, CA)
8. Crisp California Walnuts (Stratford, CA)
9. Diamond Foods, Inc. (Stockton, CA)
10. Empire Nut Company (Colusa, CA)
11. Gold River Orchards, Inc. (Escalon, CA)
12. Grower Direct Nut Company (Hughson, CA)
13. GSF Nut Company (Orosi, CA)
14. Guerra Nut Shelling Company (Hollister, CA)
15. Hill View Packing Company Inc. (Gustine, CA)
16. Linden Nut Company (Linden, CA)
17. Mariani Nut Company (Winters, CA)
18. Mariani Packing Company, Inc. (Vacaville, CA)
19. Mid Valley Nut Company Inc. (Hughson, CA)
20. National Raisin Company (Fowler, CA)
21. Poindexter Nut Company (Selma, CA)
22. Prima Noce Packing (Linden, CA)
23. Sacramento Packing, Inc. (Yuba City, CA)
24. Sacramento Valley Walnut Growers, Inc. (Yuba City, CA)
25. San Joaquin Figs, Inc. (Fresno, CA)
26. Shoei Foods USA, Inc. (Olivehurst, CA)
27. Stapleton-Spence Packing (Gridley, CA)
28. Sunsweet Growers Inc. (Yuba City, CA)
29. T.M. Duche Nut Company, Inc. (Orland, CA)
30. Wilbur Packing Company, Inc. (Live Oak, CA)
31. Valley Fig Growers (Fresno, CA)

Dated: December 11, 2014.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131, etca@trade.gov.

[FR Doc. 2014–29473 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free Trade Agreement, Article 1904; NAFTA Panel Reviews; First Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of First Request for Panel Review.

SUMMARY: On December 1, 2014, Deacero S.A.P.I. de C.V. (formerly Deacero S.A. de C.V.), and Deacero USA, Inc. filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel Review was requested of the U.S. International Trade Commission's final determination regarding Steel Concrete Reinforcing Bar from Mexico and Turkey: September 4, 2013–October 28, 2014. This determination was published in the **Federal Register** (79 FR 65,246), on November 3, 2014. The NAFTA Secretariat has assigned Case Number USA–MEX–2014–1904–02 to this request.

FOR FURTHER INFORMATION CONTACT: Marsha Ann Y. Iyomasa, Acting United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue NW., Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free Trade Agreement (''Agreement'') established a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada, and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on December 1, 2014, requesting a panel review of the determination and order described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is December 31, 2014);

(b) a Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is January 15, 2015); and

(c) the panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out

in the Complaints filed in panel review and the procedural and substantive defenses raised in the panel review.

Dated: December 10, 2014.

Marsha Ann Y. Iyomasa,

Acting United States Secretary, NAFTA Secretariat.

[FR Doc. 2014–29449 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Deep Seabed Mining Exploration Licenses

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before February 17, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Kerry Kehoe (301) 713–3155 extension 151, or *Kerry.Kehoe@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

NOAA's regulations at 15 CFR 970 govern the issuing and monitoring of exploration licenses under the Deep Seabed Hard Mineral Resources Act. Any persons seeking a license must submit certain information that allows NOAA to ensure the applicant meets the standards of the Act. Persons with licenses are required to conduct monitoring and make reports, and they may request revisions, transfers, or extensions of licenses.

II. Method of Collection

Paper submissions are used; however, applicants are encouraged to submit supporting documentation electronically when feasible.

III. Data

OMB Control Number: 0648–0145.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2.

Estimated Time per Response: Applications, 2,000–4,000 hours (no applications are expected); license renewals, 250 hours; reports, 20 hours.

Estimated Total Annual Burden Hours: 290.

Estimated Total Annual Cost to Public: $200 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 11, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–29475 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Ocean and Atmospheric Administration

Proposed Information Collection; Comment Request; West Coast Region Vessel Identification Requirements

AGENCY: National Ocean and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before February 17, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Colby Brady, (206) 526–7117 or *colby.brady@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The success of fisheries management programs depends significantly on regulatory compliance. The vessel identification requirement is essential to facilitate enforcement. The ability to link fishing (or other activity) to the vessel owner or operator is crucial to enforcement of regulations issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act. A vessel's official number is required to be displayed on the port and starboard sides of the deckhouse or hull, and on a weather deck. It identifies each vessel and should be visible at distances at sea and in the air. Law enforcement personnel rely on vessel marking information to assure compliance with fisheries management regulations. Vessels that qualify for particular fisheries are also readily identified, and this allows for more cost-effective enforcement. Cooperating fishermen also use the vessel numbers to report suspicious or non-compliant activities that they observe in unauthorized areas. The identifying number on fishing

vessels is used by the National Marine Fisheries Service (NMFS), the United States Coast Guard (USCG), and other marine agencies in issuing regulations, prosecutions, and other enforcement actions necessary to support sustainable fisheries behaviors as intended in regulations. Regulation-compliant fishermen ultimately benefit from these requirements, as unauthorized and illegal fishing is deterred and more burdensome regulations are avoided.

II. Method of Collection

Fishing vessel owners physically mark vessels with identification numbers in three locations per vessel.

III. Data

OMB Control Number: 0648–0355.

Form Number(s): None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,125.

Estimated Time per Response: 15 minutes per marking.

Estimated Total Annual Burden Hours: 69 hours.

Estimated Total Annual Cost to Public: $19,106 for materials.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost and whether the information shall have practical utility) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 11, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–29474 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Ocean and Atmospheric Administration

Proposed Information Collection; Comment Request; West Coast Region, Gear Identification Requirements

AGENCY: National Ocean and Atmospheric Administration, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before February 17, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Colby Brady, (206) 526–7117 or *colby.brady@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

The success of fisheries management programs depends significantly on regulatory compliance. The requirements that fishing gear be marked are essential to facilitate enforcement. The ability to link fishing gear to the vessel owner or operator is crucial to enforcement of regulations issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act. The marking of fishing gear is also valuable in actions concerning damage, loss, and civil proceedings. The regulations specify that fishing gear must be marked with the vessel's official number, Federal permit or tag number, or some other specified form of identification. The regulations further specify how the gear is to be marked (*e.g.,* location and color). Law enforcement personnel rely on gear marking information to assure compliance with fisheries management regulations. Gear that is not properly identified is confiscated. Gear violations are more readily prosecuted when the gear is marked, and this allows for more cost-effective enforcement. Gear marking helps ensure that a vessel harvests fish only from its own traps/pots/other gear are not illegally placed. Cooperating fishermen also use the gear marking numbers to report suspicious or non-compliant activities that they observe, and to report placement or occurrence of gear in unauthorized areas. The identifying number on fishing gear is used by the National Marine Fisheries Service (NMFS), the United States Coast Guard (USCG), and other marine agencies in issuing regulations, prosecutions, and other enforcement actions necessary to support sustainable fisheries behaviors as intended in regulations. Regulation-compliant fishermen ultimately benefit from these requirements, as unauthorized and illegal fishing is deterred and more burdensome regulations are avoided.

II. Method of Collection

The physical marking of fishing buoys is done by fishermen in the Pacific Coast Groundfish Fishery) according to regulation.

III. Data

OMB Control Number: 0648–0352.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,125.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 574 hours.

Estimated Total Annual Cost to Public: $11,351.60 for materials.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost and whether the information shall have practical utility) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 11, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–29476 Filed 12–16–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Invitation to Unmanned Rotorcraft Industry for Review and Comment Period on Edition 1 of Standardization Agreement (STANAG) 4702 Rotary Wing Unmanned Aerial Systems Airworthiness Requirements (USAR–RW)

AGENCY: United States Office of the Secretary of Defense through the United States Department of Defense for North Atlantic Treaty Organization (NATO) STANAG 4702 Custodial Support Team (CST).

ACTION: Collection of technical comments from Industry on STANAG 4702.

SUMMARY: The NATO STANAG 4702 CST is seeking a point of contact (POC) from all US Rotorcraft Industries who are interested in participating in a formal review of STANAG 4702 Edition 1 and who will provide, in writing, comments and/or concerns for review by the STANAG 4702 CST. NATO STANAG 4702 USAR–RW contains a set of technical airworthiness requirements intended for the airworthiness certification of rotary-wing military UAV Systems with a maximum take-off weight between 150 and 3175 kg that intend to regularly operate in non-segregated airspace. These requirements represent the minimum acceptable airworthiness requirements for design and construction of military rotorcraft UAVs intended to operate in non-segregated airspace. The USAR–RW is intended for application by Certifying Authorities within each country's relevant national regulatory framework. Interested participants POC information will be forwarded to the Chairman of STANAG 4702 by the US Delegation. A copy of the document will be provided to interested participants once the POC information is received by the US Delegation. The intent of this effort is to collect comments from all NATO member nation's Rotorcraft Industries, disposition the comments and at a future date hold an Industry Day to discuss comments provided in an open forum. Keywords: Helicopter, RPV, RPAS, Rotorcraft, Rotor Wing, Rotorwing, UAS, UAV, Remotely Piloted Vehicle, Vertical Take Off and Landing, VTOL, Unmanned Aircraft, Unmanned Aircraft Vehicle, Unmanned Aircraft Systems.

DATES: POC information should be provided if possible by January 7, 2015 to Mr. George L Flynn at the email address in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Collection of Technical comments from US Industry on STANAG 4702 Coordinator: Mr. George L Flynn, Email: *George.l.flynn.civ@mail.mil,* Telephone: (256) 313–6456.

Dated: December 12, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–29558 Filed 12–16–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Military Personnel Testing; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal advisory committee meeting of the Defense Advisory Committee on Military Personnel Testing. This meeting will be open to the public.

DATES: Thursday, January 15, 2015, from 9:00 a.m. to 4:00 p.m. and Friday, January 16, 2015, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: The Pine Inn, Ocean Avenue, between Lincoln and Monte Verde Street, Carmel, California.

FOR FURTHER INFORMATION CONTACT: Dr. Jane M. Arabian, Assistant Director, Accession Policy, Office of the Under Secretary of Defense (Personnel and Readiness), Room 3D1066, The Pentagon, Washington, DC 20301–4000, telephone (703) 697–9271.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to review planned changes and progress in developing computerized tests for military enlistment screening.

Agenda: The agenda includes an overview of current enlistment test development timelines, test development strategies, and planned research for the next 3 years.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public.

Committee's Designated Federal Officer or Point of Contact: Dr. Jane M. Arabian, Assistant Director, Accession Policy, Office of the Under Secretary of Defense (Personnel and Readiness), Room 3D1066, The Pentagon, Washington, DC 20301–4000, telephone (703) 697–9271. Persons desiring to make oral presentations or submit written statements for consideration at the Committee meeting must contact Dr. Jane M. Arabian at the address or telephone number in the **FOR FURTHER INFORMATION CONTACT** section no later than January 7, 2015.

Dated: December 11, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–29467 Filed 12–16–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2014–ICCD–0144]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Quick Response Information System (QRIS) 2015–2018 System Clearance

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 an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 16, 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–2014–ICCD–0144 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 Kashka Kubzdela 202–502–7411.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Quick Response Information System (QRIS) 2015–2018 System Clearance.

OMB Control Number: 1850–0733.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local or Tribal Government.

Total Estimated Number of Annual Responses: 104,004.

Total Estimated Number of Annual Burden Hours: 31,704.

Abstract: The National Center for Education Statistics (NCES) Quick Response Information System (QRIS) consists of the Fast Response Survey System (FRSS) and the Postsecondary Education Quick Information System (PEQIS). The QRIS currently conducts surveys under OMB generic clearance 1850–0733, which expires in May 2015. This submission requests approval to continue the current clearance conditions through 2018. FRSS primarily conducts surveys of the elementary/secondary sector (districts, schools) and public libraries. PEQIS conducts surveys of the postsecondary education sector. FRSS and PEQIS surveys are cleared under the QRIS generic clearance. The QRIS clearance is subject to the regular clearance process at OMB with a 60-day notice and a 30-day notice as part of the 120-day review period. Each individual FRSS or PEQIS survey is then subject to clearance process with an abbreviated clearance package, justifying the particular content of the survey, describing the sample design, the timeline for the survey activities, and the questionnaire. The review period for each individual survey is 45 days, including a 30-day **Federal Register** notice period. OMB will provide comments as soon after the end of the 30-day notice period as possible. This generic clearance request is for surveys of surveys of state education agencies, school districts, schools, postsecondary institutions, and libraries.

Dated: December 12, 2014.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2014–29559 Filed 12–16–14; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Plains & Eastern Clean Line Transmission Project Draft Environmental Impact Statement

AGENCY: Department of Energy.

ACTION: Notice of availability and public hearings.

SUMMARY: The U.S. Department of Energy (DOE) announces the availability of the *Draft Environmental Impact Statement for the Plains & Eastern Clean Line Transmission Project* (DOE/EIS–0486; Draft EIS) for a 90-day public comment period. DOE also announces 15 public hearings to receive comments on the Draft EIS. In addition, DOE invites comments on the National Historic Preservation Act Section 106 process and any potential adverse impacts to historic properties from the proposed Project. Major facilities associated with the proposed Project include converter stations in Oklahoma and Tennessee; an approximately 720-mile high voltage direct current (HVDC) transmission line; an alternating current (AC) collection system; and access roads. This Draft EIS evaluates the potential environmental impacts of the proposed Project and alternatives to it.

DATES: DOE invites comments on this Draft EIS and on the National Historic Preservation Act Section 106 process and any potential adverse impacts to historic properties from the proposed Project and alternatives during a 90-day period, which ends on March 17, 2015. Comments submitted after the close of the comment period will be considered to the extent practicable. The Department will hold 15 public hearings at the locations, dates, and start times listed in **SUPPLEMENTARY INFORMATION** below.

ADDRESSES: Written comments on the Draft EIS may be provided on the EIS Web site at *http://www.plainsandeasterneis.com* (preferred) or addressed to: Plains & Eastern EIS, 216 16th Street, Suite 1500, Denver, Colorado 80202; via email to *comments@PlainsandEasternEIS.com*; or by facsimile to (303) 295–2818. Please mark envelopes and email subject lines as *Plains & Eastern Draft EIS Comments.*

FOR FURTHER INFORMATION CONTACT: For information on the Plains & Eastern EIS or the Section 106 process, contact Jane Summerson, Ph.D., DOE NEPA Document Manager on behalf of the Office of Electricity Delivery and Energy Reliability, U.S. Department of Energy, NNSA, PO Box 391 Building 401, Kirtland Air Force Base East, Albuquerque, NM 87185; email at *Jane.Summerson01@nnsa.doe.gov*; or phone (505) 845–4091.

For general information regarding the DOE NEPA process, contact Carol Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; or phone at (202) 586–4600; voicemail at (800) 472–2756; or email at *askNEPA@hq.doe.gov*. Additional information regarding DOE's

NEPA activities is available on the DOE NEPA Web site at *http://energy.gov/nepa*.

SUPPLEMENTARY INFORMATION: In June 2010, DOE, acting through the Southwestern Power Administration and the Western Area Power Administration, both power marketing administrations within DOE, issued *Request for Proposals (RFP) for new or upgraded transmission line projects under Section 1222 of the Energy Policy Act of 2005* (75 FR 32940; June 10, 2010). In response to the RFP, Clean Line Energy Partners LLC of Houston, Texas, the parent company of Plains and Eastern Clean Line LLC and Plains and Eastern Clean Line Oklahoma LLC (collectively referred to as Clean Line or the Applicant) submitted a proposal to DOE in July 2010 for the Plains & Eastern Clean Line Project. In August 2011, Clean Line modified the proposal.

The Applicant Proposed Project would include an overhead ± 600-kilovolt (kV) HVDC electric transmission system and associated facilities with the capacity to deliver approximately 3,500 megawatts primarily from renewable energy generation facilities in the Oklahoma and Texas Panhandle regions to load-serving entities in the Mid-South and Southeast United States via an interconnection with the Tennessee Valley Authority (TVA) in Tennessee. Major facilities associated with the Applicant Proposed Project consist of converter stations in Oklahoma and Tennessee; an approximately 720-mile HVDC transmission line; an AC collection system; and access roads. Pursuant to NEPA, DOE has identified and analyzed potential environmental impacts for several alternatives in addition to the Applicant Proposed Project, including alternative routes for the HVDC transmission line and adding a converter station in Arkansas (to deliver power to the Arkansas electrical grid).

DOE has prepared this Draft EIS in consultation with the following cooperating agencies: the Bureau of Indian Affairs, Natural Resources Conservation Service, TVA, U.S. Army Corps of Engineers, U.S. Environmental Protection Agency Regions 4 and 6, and the U.S. Fish and Wildlife Service. In the Draft EIS, DOE analyzes the potential environmental impacts of the Applicant Proposed Project, the range of reasonable alternatives, and a No Action Alternative. The potential environmental impacts resulting from connected actions (wind energy generation and substation and transmission upgrades related to the Project) are also analyzed in the Draft EIS.

DOE's purpose and need for agency action is to implement Section 1222 of the Energy Policy Act of 2005. To that end, DOE needs to decide whether and under what conditions it would participate in the Applicant Proposed Project. DOE has not identified a preference for whether to participate with Clean Line in the Project in some manner as prescribed by Section 1222. DOE will identify its preference for whether to participate with Clean Line in the Applicant Proposed Project and its preferred alternatives for each of the Project elements (including route alternatives) in the Final EIS after evaluating public comments and agency input received on the Draft EIS.

Public hearings. All public hearings will follow the same format. An open house will be held from 5:00 p.m.–5:45 p.m., during which DOE and its contractors will be available to answer questions in an informal setting. Clean Line personnel also will be available to answer technical questions regarding the Project. The open house will be followed by a presentation at 5:45 p.m. by Dr. Summerson, DOE NEPA Document Manager, who will describe the Draft EIS, the NEPA and Section 106 processes, and the methods that can be used to submit comments. The formal public comment portion of the meeting will begin at 6:15 p.m. During this time, interested parties may present oral comments to DOE. A court reporter will transcribe the comments presented at each hearing. Individuals wishing to speak at a hearing should register when they arrive. DOE will initially allot three minutes to each commenter to ensure that as many people as possible have the opportunity to speak. More time may be provided, as circumstances permit. Written comments may be submitted at the hearing or by the other methods described in **ADDRESSES** above. It is DOE's practice to make comments, including names and addresses of respondents, available for public review. Before including your address, phone number, email address, or other personal identifying information with your comments, be advised that your entire comment, including your personal identifying information, may be made publicly available at any time. Although you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety. DOE will give equal consideration to oral and written comments in preparing the Final EIS. The locations, dates, and starting times of the public hearings are listed in the table below:

Date and time	Location
Monday, January 26—5:00 pm	Woodward Convention Center, 3401 Centennial Lane, Woodward, OK 73801.
Tuesday, January 27—5:00 pm	Pickle Creek Center, 822 NE 6th Street , Guymon, OK 73942.
Wednesday, January 28—5:00 pm	Beaver County Fairgrounds, Pavilion Building, 1107 Douglas Avenue, Beaver, OK 73932.
Thursday, January 29—5:00 pm	Ochiltree County Exposition Center, 402 Expo Drive , Perryton, TX 79070.
Monday, February 2—5:00 pm	Muskogee Civic Center, Room D, 425 Boston Street, Muskogee, OK 74401.
Tuesday, February 3—5:00 pm	Cushing Youth and Community Center, 700 South Little, Cushing, OK 74023.
Wednesday, February 4—5:00 pm	The Wes Watkins Center, 207 Wes Watkins Center, Exhibit Hall 111/112, (Hall of Fame and Washington), Stillwater, OK 74078.
Thursday, February 5—5:00 pm	Enid Convention Hall, Nick Benson Memorial Ballroom, 301 South Independence, Enid, OK 73701.
Monday, February 9—5:00 pm	Arkansas State University-Newport, Student Community Center, 7648 Victory Boulevard, Newport, AR 72112.
Tuesday, February 10—5:00 pm	Carmichael Community Center Auditorium, 801 S. Elm, Searcy, AR 72143.
Wednesday, February 11—5:00 pm	Arkansas State University—Marked Tree Student Center, 33500 Highway 63 E, Marked Tree, AR 72365.
Thursday, February 12—5:00 pm	Harvell Civic Center Auditorium, 8077 Wilkinsville Rd., Millington, TN 38053.
Tuesday, February 17—5:00 pm	Lake Point Conference Center—Event Center, 61 Lake Point Lane, Russellville, AR 72802.

Date and time	Location
Wednesday, February 18—5:00 pm	Fort Smith Convention Center, Exhibit Hall A, 55 7th St, Fort Smith, AR 72901.
Thursday, February 19—5:00 pm	University of Arkansas Community College at Morrilton, Fine Arts Building Auditorium, 1537 University Blvd., Morrilton, AR 72110.

Availability of the Draft EIS. The Draft EIS is available on the EIS Web site at *http://www.plainsandeasterneis.com* and on the DOE NEPA Web site at *http://nepa.energy.gov/*. A printed summary and CD of the complete document and, if preferred, a complete printed copy of the Draft EIS (approximately 3,700 pages), may be requested from *info@PlainsandEasternEIS.com*. Copies of the Draft EIS have been distributed to appropriate members of Congress, state and local government officials, American Indian tribal governments, and other federal agencies, groups, and interested parties. Copies of the complete Draft EIS and supporting documents are also available for inspection at the following locations:

Oklahoma

- Guymon Public Library—1718 N. Oklahoma St., Guymon, OK 73942
- Beaver County Pioneer Library—201 Douglas Ave., Beaver, OK 73932
- Woodward Public Library—1500 W. Main St., Woodward, OK 73801
- Muskogee Public Library—801 W. Okmulgee Ave., Muskogee, OK 74401
- Enid & Garfield County Public Library—120 W. Maine St., Enid, OK 73701
- Buffalo Public Library—11 E. Turner St., Buffalo, OK 73834
- Fairview City Library—115 S. 6th St., Fairview, OK 73737
- Guthrie Public Library—201 N. Division St., Guthrie, OK 73044
- Stillwater Public Library—1107 S. Duck St., Stillwater, OK 74955
- Chandler Public Library—1021 Manvel Ave., Chandler, OK 74834
- Montfort and Allie B. Jones Memorial Library—111 W. 7th Ave., Bristow, OK 74010
- Bartlett-Carnegie Sapulpa Public Library—27 W. Dewey Ave., Sapulpa, OK 74066
- Okmulgee Public Library—218 S. Okmulgee Ave., Okmulgee, OK 74447
- Stanley Tubbs Memorial Library—101 E. Cherokee Ave., Sallisaw, OK 74955

Arkansas

- Van Buren Public Library—1409 Main St., Van Buren, AR 72956
- Pope County Library—116 E. 3rd St., Russellville, AR 72801
- Jackson County/W.A. Billingsley Memorial Library—213 Walnut St., Newport, AR 72112
- Searcy Public Library—113 E. Pleasure Ave., Searcy, AR 72143
- Marked Tree Public Library—102 Locust St., Marked Tree, AR 72365
- Franklin County Library—120 S. 2nd St., Ozark, AR 72949
- Johnson County Library—2 Taylor Cir., Clarksville, AR 72830
- Conway County Library—101 W. Church St., Morrilton, AR 72110
- Conway Public Library—1900 W. Tyler St., Conway, AR 72034
- Mary I. Wold Cleburne County Library—1009 W. Main St., Heber Springs, AR 72543
- Poinsett County Library—200 N. East St., Harrisburg, AR 72432
- Blytheville Public Library—200 N. 5th St., Blytheville, AR 72315
- Osceola Public Library—320 W. Hale Ave., Osceola, AR 72370
- Cross County Library—410 E. Merriman Ave., Wynne, AR 72396

Tennessee

- Munford Memorial Library—1476 Munford Ave., Munford, TN 38058

Texas

- Hansford County Library—122 Main St., Spearman, TX 79081

Issued in Washington, DC, on December 11, 2014.

David S. Ortiz,

Deputy Assistant Secretary, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2014–29524 Filed 12–16–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–47–000.

Applicants: Entergy Gulf States Louisiana, L.L.C., Entergy Louisiana, LLC.

Description: Application of Entergy Gulf States Louisiana, L.L.C., and Entergy Louisiana, LLC, for FPA 203 Authorization.

Filed Date: 12/10/14.

Accession Number: 20141210–5199.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: EC15–48–000.

Applicants: Entergy Louisiana, LLC, Entergy New Orleans, Inc.

Description: Application of Entergy Louisiana, LLC and Entergy New Orleans, Inc., for FPA 203 Authorization.

Filed Date: 12/10/14.

Accession Number: 20141210–5201.

Comments Due: 5 p.m. ET 12/31/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2558–000.

Applicants: Puget Sound Energy, Inc.

Description: eTariff filing per 35.19a(b): Bellingham Cold Storage-Orchard NITSA No 709 Refund Report to be effective N/A.

Filed Date: 12/11/14.

Accession Number: 20141211–5149.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER14–2559–000.

Applicants: Puget Sound Energy, Inc.

Description: eTariff filing per 35.19a(b): Bellingham Cold Storage-Roeder NITSA No 706 Refund Report to be effective N/A.

Filed Date: 12/11/14.

Accession Number: 20141211–5148.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER14–2560–000.

Applicants: Puget Sound Energy, Inc.

Description: eTariff filing per 35.19a(b): Tesoro NITSA No 703 Refund Report to be effective N/A.

Filed Date: 12/11/14.

Accession Number: 20141211–5142.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER14–2850–002.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing per 35: Integrated System Open Access Transmission Tariff Revisions—Compliance Filing to be effective 10/1/2015.

Filed Date: 12/10/14.

Accession Number: 20141210–5157.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER14–2851–002.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing per 35: Integrated System Membership Agreement Amendments—Compliance Filing to be effective 11/10/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5155.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–522–001.

Applicants: Arizona Public Service Company.

Description: Compliance filing per 35: Errata to MBR Tariff Filing to be effective February 2, 2015 under ER15–522 to be effective 2/2/2015.

Filed Date: 12/11/14.

Accession Number: 20141211–5166.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–600–001.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: Tariff Amendment per 35.17(b): Amendment to Information Policy Changes to be effective 2/9/2015 under ER15–600 Filing Type: 130.

Filed Date: 12/11/14.

Accession Number: 20141211–5134.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–607–000.

Applicants: Duke Energy Stuart, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Amendment to Reactive Rate Schedule to be effective 12/1/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5154.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–608–000.

Applicants: Kansas City Power & Light Company.

Description: Notice of Cancellation of Interchange Agreement of Kansas City Power & Light Company.

Filed Date: 12/11/14.

Accession Number: 20141211–5033.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–610–000.

Applicants: Kansas City Power & Light Company.

Description: Notice of Cancellation of Interchange Agreement of Kansas City Power & Light Company.

Filed Date: 12/11/14.

Accession Number: 20141211–5044.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–611–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014–12–11_SA 1926 METC-Consumers 5th Rev. D–TIA to be effective 1/1/2015.

Filed Date: 12/11/14.

Accession Number: 20141211–5121.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–612–000.

Applicants: Moore Energy, LLC.

Description: Initial rate filing per 35.12 Moore Energy, LLC MBR Authority Application to be effective 2/10/2015.

Filed Date: 12/11/14.

Accession Number: 20141211–5123.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–613–000.

Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014–12–11_SA 2722 Ameren-Dynegy Construction Agreement Baldwin Upgrade to be effective 12/12/2014.

Filed Date: 12/11/14.

Accession Number: 20141211–5127.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–614–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2014–12–11_SA 2717 NSP–GRE Crooked Lake T–T to be effective 12/12/2014.

Filed Date: 12/11/14.

Accession Number: 20141211–5128.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–615–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Service Agreement No. 4052; Queue No. W3–158 to be effective 11/19/2014.

Filed Date: 12/11/14.

Accession Number: 20141211–5162.

Comments Due: 5 p.m. ET 1/2/15.

Docket Numbers: ER15–616–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Service Agreement No. 4054; Queue No. Z2–030 to be effective 11/25/2014.

Filed Date: 12/11/14.

Accession Number: 20141211–5170.

Comments Due: 5 p.m. ET 1/2/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 11, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29527 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15–255–000.

Applicants: Chesapeake Energy Marketing, L.L.C.,SND Operating, LLC.

Description: Joint Petition for Limited Waiver and Expedited Action of Chesapeake Energy Marketing, L.L.C. and SND Operating, LLC.

Filed Date: 12/9/14.

Accession Number: 20141209–5153.

Comments Due: 5 p.m. ET 12/19/14.

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.

Filings in Existing Proceedings

Docket Numbers: PR13–63–001.

Applicants: American Midstream (SIGCO Intrastate), LLC.

Description: Tariff filing per 284.123/.224: Compliance Filing (PR13–63) to be effective 12/5/2014; TOFC: 790.

Filed Date: 12/5/14.

Accession Number: 50141205–5197.

Comments Due: 5 p.m. ET 12/26/14.

284.123(g) Protests Due:

Docket Numbers: RP15–101–002.

Applicants: Florida Gas Transmission Company, LLC.

Description: Compliance filing per 154.203: Comply with RP15–101 Order regarding GTC 10 to be effective 12/1/2014.

Filed Date: 12/9/14.

Accession Number: 20141209–5187.

Comments Due: 5 p.m. ET 12/22/14.

Docket Numbers: RP15–167–001.

Applicants: High Island Offshore System, L.L.C.

Description: Compliance filing per 154.203: Capacity Release Amendment Filing to be effective 10/16/2014.

Filed Date: 12/9/14.

Accession Number: 20141209–5128.

Comments Due: 5 p.m. ET 12/22/14.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29528 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15–256–000.

Applicants: Cimarron River Pipeline, LLC.

Description: Compliance filing per 154.203: Order to Show Cause—Corrected Tariff Effective Date to be effective 10/16/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5090.

Comments Due: 5 p.m. ET 12/22/14.

Docket Numbers: RP15–257–000.

Applicants: Dauphin Island Gathering Partners.

Description: Compliance filing per 154.203: Order to Show Cause—Corrected Tariff Effective Date to be effective 10/16/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5091.

Comments Due: 5 p.m. ET 12/22/14.

Docket Numbers: RP15–258–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) rate filing per 154.204: Nicor Gas Negotiated Rate to be effective 12/10/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5122.

Comments Due: 5 p.m. ET 12/22/14.

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.

Filings in Existing Proceedings

Docket Numbers: RP14–903–001.

Applicants: SG Resources Mississippi, L.L.C.

Description: Compliance filing per 154.203: Revised Show Cause Order Compliance Filing to be effective 10/16/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5133.

Comments Due: 5 p.m. ET 12/22/14.

Docket Numbers: RP14–904–001.

Applicants: Pine Prairie Energy Center, LLC.

Description: Compliance filing per 154.203: Revised Show Cause Order Compliance Filing to be effective 10/16/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5132.

Comments Due: 5 p.m. ET 12/22/14.

Docket Numbers: RP14–905–001.

Applicants: Bluewater Gas Storage, LLC.

Description: Compliance filing per 154.203: Revised Show Cause Order Compliance Filing to be effective 10/16/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5131.

Comments Due: 5 p.m. ET 12/22/14.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 11, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29529 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2373–001.

Applicants: Avista Corporation.

Description: Compliance filing per 35: Avista Corp OATT Order 792 Compliance Filing to be effective 12/11/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5151.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–297–001.

Applicants: LDVF1 TEP LLC.

Description: Tariff Amendment per 35.17(b): Supplement to MBR Filing to be effective 1/1/2015.

Filed Date: 12/8/14.

Accession Number: 20141208–5349.

Comments Due: 5 p.m. ET 12/29/14.

Docket Numbers: ER15–567–001.

Applicants: NiGen, LLC.

Description: Tariff Amendment per 35.17(b): Amendment to Baseline Filing to be effective 1/1/2015.

Filed Date: 12/10/14.

Accession Number: 20141210–5112.

Comments Due: 5 p.m. ET 12/26/14.

Docket Numbers: ER15–602–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Service Agreement No. 4063—Queue Position Y2–078 to be effective 11/8/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5005.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–603–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2827R2 Kansas Power Pool & Westar Meter Agent Agreement to be effective 12/1/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5043.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–604–000.

Applicants: PacifiCorp.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): BPA Two-Way Operation and Maintenance Agreement 5th Revised to be effective 2/9/2015.

Filed Date: 12/10/14.

Accession Number: 20141210–5102.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–605–000.

Applicants: Solea PJM, LLC.

Description: Initial rate filing per 35.12 Solea PJM, LLC Application for MBR Authority to be effective 2/1/2015.

Filed Date: 12/10/14.

Accession Number: 20141210–5152.

Comments Due: 5 p.m. ET 12/31/14.

Docket Numbers: ER15–606–000.

Applicants: Palo Duro Wind Interconnection Services.

Description: Compliance filing per 35: Palo Duro Wind Interconnection

Services, LLC SFA Compliance Filing to be effective 10/22/2014.

Filed Date: 12/10/14.

Accession Number: 20141210–5153.

Comments Due: 5 p.m. ET 12/31/14.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29526 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP14–70–000]

National Fuel Gas Supply Corporation; Notice of Availability of the Environmental Assessment for the Proposed West Side Expansion and Modernization Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the West Side Expansion and Modernization Project (Project), proposed by National Fuel Gas Supply Corporation (National Fuel) in the above-referenced docket. National Fuel requests authorization to construct and operate natural gas pipeline facilities in Washington, Allegheny, Beaver, Venango, and Mercer Counties, Pennsylvania to provide incremental delivery of about 175,000 dekatherms per day of natural gas.

The EA assesses the potential environmental effects of the construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed Project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The proposed Project would replace about 23 miles of the existing 20-inch-diameter Line N (referred to as Sections 1, 2, and 3) which were built in 1947, with new 24-inch-diameter pipeline located in Washington, Allegheny, and Beaver Counties. The replacement section is proposed to be constructed at an approximately 25-foot offset from the existing pipeline where feasible.

The Project also consists of the installation of additional compression at the existing Mercer Compressor Station in Mercer County and miscellaneous piping modifications at the existing Henderson Compressor Station in Venango County. The modifications at the Henderson Compressor Station are necessary to meet the changing pipeline operating conditions with the addition of the new service. National Fuel currently owns the land required to construct and operate the additional compression and station modifications.

The FERC staff mailed copies of the EA to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding.

In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before January 9, 2015.

For your convenience, there are three methods you can use to file your comments with the Commission. In all instances please reference the Project docket number (CP14–70–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at 202–502–8258 or *efiling@ferc.gov*.

(1) You may file your comments electronically using the *eComment* feature located on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a Project.

(2) You may file your comments electronically using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister*.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing.''

(3) You may file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP14–70). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission,

[1] See the previous discussion on the methods for filing comments.

such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29541 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR15–4–000]

Enbridge Energy, Limited Partnership; Notice of Filing of Supplement to Facilities Surcharge Settlement

Take notice that on December 1, 2014, Enbridge Energy, Limited Partnership (Enbridge Energy), with the support of the Canadian Association of Petroleum Producers (CAPP), submitted a Supplement to the Facilities Surcharge Settlement approved by the Commission on June 30, 2004, in Docket No. OR04–2–000, at 107 FERC ¶ 61,336 (2004).

In accordance with Rule 602(f) of the Commission's Rules of Practice and Procedure, 18 CFR 385.602(f), any person desiring to comment on this Supplement should file its comments with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 29, 2014.

Dated: December 10, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29531 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–605–000]

Solea PJM, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding, of Solea PJM, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and *Procedure* (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is **December 31, 2014**.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 11, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–29530 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–20–000]

DCP Midstream, LP; Notice of Request Under Blanket Authorization

Take notice that on December 1, 2014, DCP Midstream, LP (DCP), 370 17th Street, Suite 2500, Denver, Colorado 80202, filed in Docket No. CP15–20–000, a prior notice request pursuant to sections 157.205, 157.210, and 157.216 of the Commission's regulations under the Natural Gas Act (NGA) as amended, requesting authorization to modify its Lucerne Residue Pipeline. Specifically, DCP proposes to: (i) Abandon 1.3 miles of 16-inch diameter pipeline from interstate transmission to non-jurisdictional gathering (16-inch Pipeline); (ii) acquire 1.3 miles of 10-inch diameter non-jurisdictional gathering pipeline for use as interstate transmission (10-inch Pipeline); and (iii) to connect the 10-inch Pipeline to the

Lucerne Residue Pipeline (collectively, the Project). DCP asserts that Project will provide necessary capacity to DCP's non-jurisdictional gathering system that delivers gas from the Niobrara Shale to DCP's Lucerne Plants without impacting the certificated capacity of the Lucerne Residue Pipeline. DCP estimates the cost of the Project to be approximately $300,000, 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, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Katie Rice, DCP Midstream, LP, 370 17th Street, Suite 2500, Denver, Colorado 80202, by telephone at (303) 605–2166, by facsimile at (303) 605–2226, or by email at *kerice@dcpmistream.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

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.

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 commenter's 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 commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29542 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR15–5–000]

Sunoco Pipeline L.P.; SunVit Pipeline LLC; ExxonMobil Pipeline Company; Notice of Petition for Declaratory Order

Take notice that on December 5, 2014, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2014), Sunoco Pipeline L.P., SunVit Pipeline LLC, and ExxonMobil Pipeline Company (collectively, the Petitioners) filed a petition for declaratory order approving the specified rate structures, terms of service, and prorationing methodology for the proposed Permian Longview and Louisiana Extension pipeline project, as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on January 9, 2015.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29544 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–9–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section

30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Check 8 on Westside Main Canal In-Conduit Hydroelectric Project would have an installed capacity of 745 kilowatts (kW) and would be located on the existing Westside Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Imperial in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) One proposed 35-foot-long, 31-foot-wide open concrete canal intake structure with two 10-foot wide gates; (2) a proposed 15- by 36-foot powerhouse containing two turbine generator units with a total installed capacity of 745 kW; (3) the proposed 110-foot-long, 31-foot-wide underground closed concrete box tailrace structure which returns the water into the Westside Main Canal; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 3,990 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–9–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

[1] 18 CFR 385.2001–2005 (2014).

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29537 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–6–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Tuberose

Check on Westside Main Canal In-Conduit Hydroelectric Project would have an installed capacity of 410 kilowatts (kW) and would be located on the existing Westside Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Brawley in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) One proposed 19.8-foot-long, 31.4-foot-wide concrete box intake structure with two 10-foot wide gates; (2) a proposed 15- by 36-foot powerhouse containing two turbine generator units with a total installed capacity of 410 kW; (3) the proposed 95-foot-long, 31.4-foot-wide concrete box tailrace structure which returns the water into the Westside Main Canal; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 2,307 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–6–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29534 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–11–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Dahlia Check on Central Main Canal In-Conduit Hydroelectric Project would have an installed capacity of 285 kilowatts (kW) and would be located on the existing Central Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The

project would be located near the city of El Centro in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) A proposed 25-foot-long, 20-foot-wide open concrete canal intake structure with one 10-foot-wide gates; (2) a proposed 15- by 20-foot powerhouse containing one turbine generator unit with an installed capacity of 285 kW; (3) the proposed 69-foot-long, 20-foot-wide open concrete box tailrace structure which returns the water into the Central Main Canal; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 1,369 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–11–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29538 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–4–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Newside Check on Central Main Canal In-Conduit Hydroelectric Project would have an installed capacity of 430 kilowatts (kW) and would be located on the existing Central Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Imperial in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov*.

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) one proposed 37.7-foot-long, 16.8-foot-wide concrete box intake structure with a 10-foot wide gate; (2) a proposed 15- by 22-foot powerhouse containing a turbine generator unit with an installed capacity of 430 kW; (3) a proposed 36-foot-long, 16.8-foot-wide concrete box tailrace structure which returns the water into the Central Main Canal; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 2,201 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–4–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659.

[1] 18 CFR 385.2001–2005 (2014).

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29532 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–8–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Check 4 on Central Main Canal In-Conduit Hydroelectric Project would have an installed capacity of 315 kilowatts (kW) and would be located on the existing Central Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Brawley in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed

project would consist of: (1) One proposed 27.6-foot-long, 10-foot-wide open concrete canal intake structure with one 10-foot wide gate; (2) a proposed 15- by 25-foot powerhouse containing the turbine generator unit with an installed capacity of 315 kW; (3) the proposed 125-foot-long, 12-foot-wide concrete box tailrace structure which returns the water into the Central Main Canal; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 1,613 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–8–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29536 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–12–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Drop 2 on Central Drain In-Conduit Hydroelectric Project would have an installed capacity of 300 kilowatts (kW) and would be located on the existing Central Drain approximately 250 feet upstream from its convergence with the Alamo River. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Holtville in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) A proposed 27.21-foot-long, 14-foot-wide open concrete canal intake structure with one 10-foot wide gate; (2) a proposed 15- by 20-foot powerhouse containing one turbine generator unit with an installed capacity of 300 kW; (3) the proposed

200-foot-long, 14-foot-wide open canal tailrace structure which returns the water into the Alamo River approximately 150 feet downstream of the convergence of the Central Drain and Alamo River; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 1,292 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–12–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29539 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–7–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Westside Main Canal Heading In-Conduit Hydroelectric Project would have an installed capacity of 1,045 kilowatts (kW) and would be located on the existing Westside Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Calexico in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) one proposed 81-foot-long, 52-foot-wide covered concrete canal intake structure with three 10-foot-wide gates; (2) a proposed 15- by 60-foot powerhouse containing three turbine generator units with a total installed capacity of 1,045 kW; (3) the proposed 47-foot-long, 52-foot-wide concrete box tailrace structure which returns the water into the

Westside Main Canal; and (4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 5,938 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–7–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29535 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–16–000]

Imperial Irrigation District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On November 26, 2014, the Imperial Irrigation District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Fillaree Check on Westside Main Canal In-Conduit Hydroelectric Project would have an installed capacity of 675 kilowatts (kW) and would be located on the existing Westside Main Canal. This conduit transports water for irrigation, municipal, and industrial purposes. The project would be located near the city of Edgar in Imperial County, California.

Applicant Contact: Carl Stills, 1651 West Main Street, El Centro, CA 92243, Phone No. (760) 339–9701.

FERC Contact: Robert Bell, Phone No. (202) 502–6062, email: *robert.bell@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) A proposed 20.2-foot-long, 35.8-foot-wide open concrete canal intake structure with two 10-foot wide gates; (2) a proposed 15- by 41-foot powerhouse containing two turbine generator units with a total installed capacity of 675 kW; (3) the proposed 184-foot-long, 35.8-foot-wide underground closed concrete box tailrace structure which returns the water into the Westside Main Canal; and

(4) appurtenant facilities. The proposed project would have an estimated annual generating capacity of 3,241 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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. 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.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*e.g.,* CD15–16–000) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–29540 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–37–000]

PJM Interconnection, L.L.C.; Supplemental Notice of Technical Conference

As announced in a Notice issued on October 31, 2014, the Federal Energy Regulatory Commission (Commission) will hold a technical conference on Wednesday, January 7, 2015. The technical conference will explore whether: 1) PJM Interconnection, L.L.C.'s (PJM) Financial Transmission Rights (FTR) forfeiture rule as it applies to Up-to Congestion (UTC) transactions and virtual (INC/DEC) transactions is just and reasonable; and 2) PJM's current uplift allocation associated with UTC transactions and INCs/DECs is just and reasonable. The technical conference will commence at 9:00 a.m. and conclude at 4:30 p.m. and be held at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. This technical conference is free of charge and open to the public. Commission members may participate in the technical conference.

The agenda and a list of participants for this technical conference are attached.

Those who plan to attend the technical conference are encouraged to complete the registration form located at: *https://www.ferc.gov/whats-new/registration/01-07-15-form.asp.* There is no registration deadline.

The technical conference will be transcribed. Transcripts of the technical conference will be available for a fee from Ace-Federal Reporters, Inc. (202–347–3700 or 1–800–336–6646). Additionally, there will be a free

Webcast of the technical conference. The webcast will allow persons to listen to the technical conference but not participate. Anyone with Internet access who wants to listen to the technical conference can do so by navigating to the Calendar of Events at *www.ferc.gov,* locating the technical conference in the Calendar, and clicking on the webcast link. The Capitol Connection provides technical support for the Webcast and offers the option of listening to the meeting via phone-bridge for a fee. If you have any questions, visit *www.CapitolConnection.org* or call 703–993–3100.

While this technical conference is not for the purpose of discussing specific cases, the technical conference may address matters at issue in the following, related Commission proceeding that is pending: ER13–1654–001.

Commission technical conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 502–8659 (TTY), or send a fax to (202) 208–2106 with the requested accommodations.

For more information about the technical conference, please contact:

Sarah McKinley (Logistical Information), Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8368, *sarah.mckinley@ferc.gov*.

Carmen Gastilo Machuga (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8657, *carmen.gastilo@ferc.gov*.

William Sauer (Technical Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6639, *william.sauer@ferc.gov*.

Cathleen Colbert (Technical Information), Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8997, *cathleen.colbert@ferc.gov*.

Dated: December 10, 2014.

Kimberly D. Bose,

Secretary.

Technical Conference on Financial Transactions in PJM

Docket No. EL14–37–000

January 7, 2015

Agenda

The technical conference will explore whether: (1) PJM's FTR forfeiture rule as it applies to UTC transactions and INCs/DECs is just and reasonable; and (2) PJM's current uplift allocation associated with UTC transactions and INCs/DECs is just and reasonable. Presentations will be allowed at the beginning of each Panel. Any presentations should be narrowly confined to the topics discussed in this agenda and should be no longer than five minutes. Presentations should primarily focus on factual background. Presentations and discussions should be confined to proposals for addressing these issues within PJM.

9:00am–9:15am Welcome and Opening Remarks

9:15am–12:00pm Panel 1: FTR Forfeiture Rule Goals and Designs (with a 15 minute break)

Panel 1 will explore PJM's FTR forfeiture rule as it applies to INCs/DECs and UTC transactions. In the context of applying the rule to these products, the Panel will discuss: (1) the goals of the FTR forfeiture rule; and (2) different ways of structuring the FTR forfeiture rule's design.

During the discussion on goals, Panelists should be prepared to address the following:

- The FTR forfeiture rule was intended to address potential market abuse.[1] The market abuse in question was trading to create artificial congestion in the day-ahead market that influenced the value of FTRs, conduct which may be a violation of the Anti-Manipulation Rule after its implementation in 2006. INCs/DECs and UTC transactions may provide value to the system by improving price convergence. Given these two priorities, is it possible to design an effective rule that addresses market abuse yet does not discourage legitimate virtual trading that can contribute to price convergence?
- Examples of how INCs/DECs and UTC transactions influence the value of FTRs
- Behaviors to be discouraged or encouraged through the FTR forfeiture rule

During the discussion on different ways of structuring the FTR forfeiture rule design, Panelists should be prepared to address the structural components of an effective rule, including:

- In which way, if at all, should transactions be aggregated to determine the effect on congestion? In determining the effect on congestion, should the FTR forfeiture rule consider each market participant's portfolio of transactions? If so, is this approach technically feasible?
- In which way, if at all, should the FTR forfeiture rule assess INCs/DECs and UTC transactions that are intended to relieve congestion to benefit the value of counter-flow FTRs?
- At what threshold should the flow impact on a transmission constraint's limit trigger the forfeiture? What are the possible implications of implementing an overly strict rule versus a rule that may fail to identify all instances of potentially manipulative behavior?
- How, if at all, should the rule treat INCs/DECs and UTC transactions

[1] December 22, 2000 filing of PJM Interconnection, L.L.C., Docket No. ER01–773–000 at 2 (''The purpose of the modifications is to address concerns . . . that an entity can purchase FTRs in the monthly FTR auction and then enter Increment and Decrement Bids in the Day-ahead Market so as to create congestion and artificially (continued . . .) increase the value of its FTRs.'').

differently under various rule designs? For instance, should different injection/withdrawal points be utilized? Should different forfeiture thresholds be used?

Panelists:

- Andrew Hartshorn, Boston Energy Trading and Marketing
- Noha Sidhom, Inertia Power, LP
- Harry Singh, J. Aron & Company
- Joseph Bowring, Monitoring Analytics
- Stu Bresler, PJM Interconnection, L.L.C.

12:00pm–1:00pm Lunch

1:00pm–4:15pm Panel 2: Uplift Causation and Allocation (with a 15 minute break)

Panel 2 will explore the circumstances under which INCs/DECs and UTC transactions may cause uplift in PJM and, if so, how INCs/DECs and UTC transactions should be allocated uplift charges. In the context of assessing PJM's uplift allocation, the Panel will discuss: (1) the extent to which uplift may be caused by INCs/DECs and UTC transactions; and (2) different ways to potentially allocate uplift to INCs/DECs and UTC transactions.

During the discussion on uplift causation, Panelists should be prepared to address the following:

- How, if at all, do INCs/DECs and UTC transactions cause uplift?
- In which way, if at all, is uplift caused by INCs/DECs and UTC transactions associated with congestion, divergences between day-ahead and real-time physical energy requirements, or other positions held by each market participant?
- Are there methods available to accurately and dynamically determine any uplift that may be caused by INCs/DECs and UTC transactions?

During the discussion on uplift allocation, Panelists should be prepared to address the following:

- The status of PJM's Energy Market Uplift Senior Task Force.
- What principle(s) should be followed if and when allocating uplift to INCs/DECs and UTC transactions? For instance, one potential solution is that uplift costs should be strictly allocated based on cost causation determinations. Other potential solutions may be guided by simplicity, predictability, or multiple objectives. What new, if any, uplift allocation rules should be implemented based on this principle(s)?
- Under which, if any, circumstances should INCs/DECs and UTC transactions be offset by other transactions to limit uplift allocation exposure?

Panelists:

- Abram Klein, Appian Way Energy Partners
- William Hogan, Harvard University, speaking on behalf of Financial Marketers Coalition
- Joseph Bowring, Monitoring Analytics
- Adam Keech, PJM Interconnection, L.L.C.
- David Patton, Potomac Economics, Ltd.
- Wesley Allen, Red Wolf Energy Trading, L.L.C.
- Stephanie Staska, Twin Cities Power Holdings, L.L.C.
- Michael McNair, Yes Energy

4:15pm–4:30pm Closing

[FR Doc. 2014–29543 Filed 12–16–14; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0014; FRL–9920–12]

Product Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1 of Unit II., pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows an April 11, 2014 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 of Unit II. to voluntarily cancel these product registrations. In the April 11, 2014 **Federal Register** notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 180 day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency received comments on the April 11, 2014 **Federal Register** notice but none merited its further review of the requests. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective December 17, 2014.

FOR FURTHER INFORMATION CONTACT: Janeese Hackley, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 605–1523; email address: *hackley.janeese@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2010–0014, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the agency taking?

This notice announces the cancellation, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

EPA registration No.	Product name	Chemical name
000264–00941	Gustafson Baytan 30 Flowable Fungicide	Triadimenol.
000264–00948	Gustafson LSP Flowable Fungicide	Thiabendazole.
000264–01036	Trilex Advanced Pak	Metalaxyl, triadimenol, and trifloxystrobin.
005383–00068	Troysan 174P	2-((Hydroxymethyl)amino) ethanol.
035935–00066	Trinexapac-ethyl Technical	Trinexapac-ethyl.
AZ–080015	Proclipse 65 WDG	Prodiamine.
CA–080022	Proclipse 65 WDG	Prodiamine.
LA–090001	Dual Magnum	*S*-Metolachlor.
ND–030001	Apron MAXX RTA	Fludioxonil and metalaxyl-*M*.
ND–030002	Apron MAXX RTA	Fludioxonil and metalaxyl-*M*.
OR–080034	Evito 480 SC Fungicide	Fluoxastrobin.
OR–100007	Bird Shield Bird Repellent Concentrate	Methyl anthranilate.
TX–090007	Gramoxone Inteon	Paraquat dichloride.
WA–090009	Retain Plant Growth Regulator Soluble Powder	3-Butenoic acid, 2-amino-4-(2-aminoethoxy)-, monohydrochloride, (*S*-(*E*))-,.
WA–120013	Sevin Brand 4F Carbaryl Insecticide	Carbaryl.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 of this unit.

TABLE 2—REGISTRANTS OF CANCELLED PRODUCTS

EPA company No.	Company name and address
264	Bayer CropScience, LP, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709.
5383	Troy Chemical Corporation, 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200.
35935	Nufarm Limited Agent: Nufarm Limited, 4020 Aerial Center Pkwy., Suite 103, Morrisville, NC 27560.
AZ–080015, CA–080022.	Nufarm Americas, Inc., Agent: Nufarm Americas, Inc. 4020 Aerial Center Pkwy., Suite 101, Morrisville, NC 27560.
LA–090001, ND–030001, ND–030002, TX–090007.	Syngenta Crop Protection, LLC, 410 Swing Rd., P.O. Box 18300 Greensboro, NC 27419–8300.
OR–080034	Arysta Lifescience North America, LLC, 15401 Weston Pkwy., Suite 150, Cary, NC 27513.
OR–100007	Bird Shield Repellent Corporation, 254 E. Main St., Suite 226A, P.O. Box 785, Pullman, WA 99163.
WA–090009	Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048–6316.

TABLE 2—REGISTRANTS OF CANCELLED PRODUCTS—Continued

EPA company No.	Company name and address
WA–120013	Tessenderlo Kerley, Inc., Agent: Pyxis Regulatory Consulting, Inc., 4110 136th St. NW., Gig Harbor, WA 98332.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period, EPA received one comment. The comment did not contain information about any specific product cancellation request. For this reason, the Agency does not believe that the comment submitted during the comment period merit further review or a denial of the request for voluntary cancellation.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested cancellations of the registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II. are canceled. The effective date of the cancellations that are the subject of this notice is December 17, 2014. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of April 11, 2014 (79 FR 20200) (FRL–9908–81). The comment period closed on October 8, 2014.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The existing stocks provisions for the products subject to this order are as follows.

The registrants may continue to sell and distribute existing stocks of products listed in Table 1 of Unit II. until December 17, 2015, which is 1 year after the publication of the cancellation order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II., except for export in accordance with FIFRA section 17 (7 U.S.C. 136o), or proper disposal. Persons other than the registrants may sell, distribute, or use existing stocks of products listed in Table 1 of Unit II. until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 5, 2014.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2014–29583 Filed 12–16–14; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Notice of Submission for OMB Review; Comment Request

AGENCIES: Equal Employment Opportunity Commission.

ACTION: Notice of information collection—Uniform Guidelines on Employee Selection Procedures—Extension Without Change.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Equal Employment Opportunity Commission gives notice of its intent to submit to the Office of Management and Budget (OMB) a request for renewal of the information collection described below.

DATES: Written comments on this notice must be submitted on or before February 17, 2015.

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

- By mail to Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.
- By facsimile (''FAX'') machine to (202) 663–4114. (There is no toll free FAX number.) Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTD). (These are not toll free numbers).
- By the Federal eRulemaking Portal: *http://www.regulations.gov.* After accessing this Web site, follow its instructions for submitting comments.

Comments need be submitted in only one of the above-listed formats, not all three. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information you provide. Copies of the received comments also will be available for inspection in the EEOC Library, FOIA Reading Room, by advance appointment only, from 9 a.m. to 5 p.m., Monday through Friday, except legal holidays, from February 17, 2015. Persons who schedule an appointment in the EEOC Library, FOIA Reading Room, and need assistance to view the comments will be provided with appropriate aids upon request, such as readers or print magnifiers. To schedule an appointment to inspect the comments at the EEOC Library, FOIA Reading Room, contact the EEOC Library by calling (202) 663–4630 (voice) or (202) 663–4641 (TTY). (These are not toll free numbers).

FOR FURTHER INFORMATION CONTACT: Kathleen Oram, Senior Attorney, at (202) 663–4681 (voice), or Thomas J. Schlageter, Assistant Legal Counsel, (202) 663–4668 (voice) or (202) 663–7026 (TDD).

SUPPLEMENTARY INFORMATION:

Introduction

The Equal Employment Opportunity Commission (EEOC or Commission) gives notice of its intent to submit the recordkeeping requirements contained in the Uniform Guidelines on Employee Selection Procedures (UGESP or Uniform Guidelines) [1] to the Office of Management and Budget (OMB) for a three-year extension without change under the Paperwork Reduction Act of 1995 (PRA). Concurrent with this notice, EEOC is requesting OMB approval for a brief emergency extension of the UGESP recordkeeping requirement to begin immediately after the current December 31, 2014 expiration date.

Request for Comments

Pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, and OMB regulation 5 CFR 1320.8(d)(1), the EEOC invites public comments that will enable the agency to:

(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 the agency's 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of Collection

Collection Title: Recordkeeping Requirements of the Uniform Guidelines on Employee Selection Procedures, 29 CFR part 1607, 41 CFR part 60–3, 28 CFR part 50, 5 CFR part 300.

OMB Number: 3046–0017.

Type of Respondent: Businesses or other institutions; Federal Government; State or local governments and farms.

North American Industry Classification System (NAICS) Code: Multiple.

Standard Industrial Classification Code (SIC): Multiple.

Description of Affected Public: Any employer, Government contractor, labor organization, or employment agency covered by the Federal equal employment opportunity laws.

Respondents: 914,843.

Responses: [2] 914,843.

Recordkeeping Hours: 6,372,498 per year.

Number of Forms: None.

Form Number: None.

Frequency of Report: None.

Abstract: The Uniform Guidelines provide fundamental guidance for all Title VII-covered employers about the use of employment selection procedures. The records addressed by UGESP are used by respondents to ensure that they are complying with Title VII and Executive Order 11246; by the Federal agencies that enforce Title VII and Executive Order 11246 to investigate, conciliate, and litigate charges of employment discrimination; and by complainants to establish violations of Federal equal employment opportunity laws. While there is no data available to quantify these benefits, the collection of accurate applicant flow data enhances each employer's ability to address any deficiencies in recruitment and selection processes, including detecting barriers to equal employment opportunity.

Burden Statement: There are no reporting requirements associated with UGESP. The burden being estimated is the cost of collecting and storing a job applicant's gender, race, and ethnicity data. The only paperwork burden derives from this recordkeeping.

Only employers covered under Title VII and Executive Order 11246 are subject to UGESP. For the purpose of burden calculation, employers with 15 or more employees are counted. The number of such employers is estimated at 914,843, which combines estimates

[1] 29 CFR. part 1607, 41 CFR part 60–3, 28 CFR part 50, 5 CFR part 300.

[2] The number of respondents is equal to the number of responses (*i.e.* one response per person).

from private employment,[3] the public sector,[4] colleges and universities,[5] and referral unions.[6]

This burden assessment is based on an estimate of the number of job applications submitted to all Title VII-covered employers in one year, including paper-based and electronic applications. The total number of job applications submitted every year to covered employers is estimated to be 1,529,399,487, based on a National Organizations Survey [7] average of approximately 35 applications [8] for every hire and a Bureau of Labor Statistics data estimate of 43,414,608 annual hires.[9] This figure also includes 119,920 applicants for union membership reported on the EEO–3 form for 2012.

The employer burden associated with collecting and storing applicant demographic data is based on the following assumptions: Applicants would need to be asked to provide three pieces of information—sex, race/ethnicity, and an identification number (a total of approximately 13 keystrokes); the employer would need to transfer information received to a database either manually or electronically; and the employer would need to store the 13 characters of information for each applicant. Recordkeeping costs and burden are assumed to be the time cost associated with entering 13 keystrokes.

Assuming that the required recordkeeping takes 30 seconds per record, and assuming a total of 1,529,399,487 paper and electronic applications per year (as calculated above), the resulting UGESP burden hours would be 6,372,498. Based on a wage rate of $15.48 per hour for the individuals entering the data, the collection and storage of applicant demographic data would come to approximately $98,646,267 per year for Title VII-covered employers. We expect that the foregoing assumptions are over-inclusive, because many employers have electronic job application processes that should be able to capture applicant flow data automatically.

While the burden hours and costs for the UGESP recordkeeping requirement seem very large, the average burden per employer is relatively small. We estimate that UGESP applies to 914,843 employers. Therefore the cost per covered employer is less than $108 ($98,646,267 divided by 914,843 is equal to $107.87). Additionally UGESP allows for simplified recordkeeping for employers with more than 15 but less than 100 employees.[10]

Dated: December 11, 2014.

Jenny R. Yang,

Chair, Equal Employment Opportunity Commission.

[FR Doc. 2014–29593 Filed 12–16–14; 8:45 am]

BILLING CODE 6570–01–P

[3] Source: Census Bureau 2011 County Business Patterns: Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States and States, Totals: 2011, Release Date 12.13. *(https://www.census.gov/econ/susb/.) Select U.S. & states, Totals. Downloaded on October 2, 2014.*

[4] Source of original data: 2012 Census of Governments: Employment. Individual Government Data File (*http://www.census.gov/govs/apes/*), Local Downloadable Data zip file 12ind_all_tabs.xls. The original number of government entities was adjusted to only include those with 15 or more employees.

[5] Source: U.S. Department of Education, National Center for Education Statistics, IPEDS, Fall 2013. Number and percentage distribution of Title IV institutions, by control of institution, level of institution, and region: United States and other U.S. jurisdictions, academic year 2013–1(*http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2014066rev*).

[6] EEO–3 Reports filed by referral unions in 2012 with EEOC.

[7] The National Organizations Survey is a survey of business organizations across the United States in which the unit of analysis is the actual workplace (*http://www.icpsr.umich.edu/icpsrweb/ICPSR/studies/04074*).

[8] The number of applications provided by NOS is 35.225 and therefore calculations will not result in the same total amount due to rounding.

[9] Bureau of Labor Statistics Job Openings and Labor Turnover Survey, 2013 annual level data (Not seasonally adjusted), (*http://www.bls.gov/jlt/data.htm*) is the source of the original data. The BLS figure (50,718,000) has been adjusted to only include hires by firms with 15 or more employees.

[10] *See* 29 CFR 1607.15A(1): *Simplified recordkeeping for users with less than 100 employees.* In order to minimize recordkeeping burdens on employers who employ one hundred (100) or fewer employees, and other users not required to file EEO–1, *et seq.,* reports, such users may satisfy the requirements of this section 15 if they maintain and have available records showing, for each year: (a) The number of persons hired, promoted, and terminated for each job, by sex, and where appropriate by race and national origin; (b)The number of applicants for hire and promotion by sex and where appropriate by race and national origin; and (c) The selection procedures utilized (either standardized or not standardized).

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Information Collection Revision; Comment Request (3064–0189)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of Information Collection To Be Submitted to OMB for Review and Approval Under the Paperwork Reduction Act, and Request for Comment

SUMMARY: The Federal Deposit Insurance Corporation (''FDIC'') invites the general public and other Federal agencies to take this opportunity to comment on a revision of a continuing information collection, titled, ''Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of $50 Billion or More under the Dodd-Frank Wall Street Reform and Consumer Protection Act,'' (3064–0189), as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received by January 16, 2015.

ADDRESSES: You may submit written comments by any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC Web site.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Comments@FDIC.gov.* Include ''Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of $50 Billion or More'' on the subject line of the message.
- *Mail:* Gary A. Kuiper, Counsel, or John Popeo, Counsel, Legal Division, Attention: Comments, FDIC, 550 17th Street NW., MB–3098, Washington, DC 20429.
- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.
- *Public Inspection:* All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/* including any personal information provided.

Additionally, you may send a copy of your comments: By mail to the U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503 or by facsimile to 202.395.6974, Attention: Federal Banking Agency Desk Officer.

FOR FURTHER INFORMATION CONTACT: You can request additional information from John Popeo (202.898.6923), or Gary Kuiper (202.898.3877), Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., MB–3098, Washington, DC 20429. In addition, copies of the templates referenced in this notice can be found on the FDIC's Web site (*http://www.fdic.gov/regulations/laws/federal/*).

SUPPLEMENTARY INFORMATION: The FDIC is requesting comment on the following changes to the information collection:

Title: Company-Run Annual Stress Test Reporting Template and Documentation for Covered Institutions with Total Consolidated Assets of $50 Billion or More under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

OMB Control Number: 3064–0189

Description: Section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act [1] (''Dodd-Frank Act'') requires certain financial companies, including state nonmember banks and state savings associations, to conduct annual stress tests [2] and requires the primary financial regulatory agency [3] of those financial companies to issue regulations implementing the stress test requirements.[4] A state nonmember bank or state savings association is a ''covered bank'' and therefore subject to the stress test requirements if its total consolidated assets are more than $10 billion. Under section 165(i)(2), a covered bank is required to submit to the Board of Governors of the Federal Reserve System (Board) and to its primary financial regulatory agency a report at such time, in such form, and containing such information as the primary financial regulatory agency may require.[5]

On October 15, 2012, the FDIC published in the **Federal Register** a final rule implementing the section 165(i)(2) annual stress test requirement.[6] The final rule requires covered banks to meet specific reporting requirements under section 165(i)(2). In 2012, the FDIC first implemented the reporting templates for covered banks with total consolidated assets of $50 billion or more and provided instructions for completing the reports.[7] This information collection notice describes revisions by the FDIC to those reporting templates and related instructions, as well as required information. The information contained in these information collections may be given confidential treatment to the extent allowed by law (5 U.S.C. 552(b)(4)).

Consistent with past practice, the FDIC intends to use the data collected to assess the reasonableness of the stress test results of covered banks and to provide forward-looking information to the FDIC regarding a covered institution's capital adequacy. The FDIC also may use the results of the stress tests to determine whether additional analytical techniques and exercises could be appropriate to identify, measure, and monitor risks at the covered bank. The stress test results are expected to support ongoing improvement in a covered bank's stress testing practices with respect to its internal assessments of capital adequacy and overall capital planning.

The FDIC recognizes that many covered banks with total consolidated assets of $50 billion or more are required to submit reports using the Board's Comprehensive Capital Analysis and Review (''CCAR'') reporting form, FR Y–14A. The FDIC also recognizes the Board has modified the FR Y–14A, and the FDIC will keep its reporting requirements as similar as possible with the Board's FR Y–14A in order to minimize burden on affected institutions. Therefore, the FDIC is revising its reporting requirements to remain consistent with the Board's FR Y–14A for covered banks with total consolidated assets of $50 billion or more.

Revisions to Reporting Templates for Institutions With $50 Billion or More in Assets

On July 9, 2013, the FDIC approved an interim final rule that will revise and replace the FDIC's risk-based and leverage capital requirements to be consistent with agreements reached by the Basel Committee on Banking Supervision in ''Basel III: A Global Regulatory Framework for More Resilient Banks and Banking Systems'' (''Basel III'').[8] The final rule was published in the **Federal Register** on April 14, 2014 (''Revised Capital Framework'').[9] The revisions include implementation of a new definition of regulatory capital, a new common equity tier 1 minimum capital requirement, a higher minimum tier 1 capital requirement, and, for banking organizations subject to the Advanced Approaches capital rules, a supplementary leverage ratio that incorporates a broader set of exposures in the denominator measure. In addition, the rule will amend the methodologies for determining risk weighted assets. All banking organizations that are not subject to the Advanced Approaches Rule must begin to comply with the Revised Capital Framework on January 1, 2015.

Due to the timing of the Dodd-Frank Act stress test and the revised capital rulemaking, the FDIC considered several options for the timing and scope of this proposal to collect information related to the capital rulemaking. On September 30, 2014, the FDIC published in the **Federal Register**, a 60-day information collection notice requesting public comment on proposed revisions to the DFAST–14A stress testing reporting templates.[10] The FDIC received no comments on the proposed changes to the DFAST–14A stress testing reporting templates. The revisions to the DFAST–14A reporting templates consist of adding data items, deleting data items, and redefining existing data items. These changes will provide additional information to greatly enhance the ability of the FDIC to analyze the validity and integrity of firms' projections, improve comparability across firms, and increase consistency between the FR Y–14A reporting templates and DFAST–14A reporting templates. The FDIC has conducted a thorough review of the changes and believes that the incremental burden of these changes is justified given the need for these data to properly conduct the FDIC's supervisory responsibilities related to the stress testing.

Summary Schedule

Revisions to Income Statement Sub-Schedule

Under the current reporting template,, there is a definitional difference between the realized gains (losses) on available-for-sale (''AFS'') and held-to-maturity (''HTM'') securities reported on the Income Statement (items 127 and 128) and the AFS and HTM totals computed on sub-schedule A.3.c (Projected Other-Than-Temporary Impairment (''OTTI'') for AFS and HTM Securities by Portfolio), resulting from the Revised Capital Framework. In order to accurately collect information for the Income Statement, the FDIC proposes changing items 127 and 128 to be reported items instead of being equal to the total amounts on sub-schedule A.3.c. Additionally, for consistency with changes proposed to sub-schedule A.5 (Counterparty Risk) described below, items 59 and 62 (Trading Incremental Default Losses and Other CCR Losses) would be modified to be Trading Issuer Default Losses and CCR Losses, and line item 61 (Counterparty Incremental Default Losses) would be removed.

Revisions to RWA and Capital Sub-Schedules

To better align the collection of regulatory capital components with

[1] Public Law 111–203, 124 Stat. 1376 (July 21, 2010).

[2] 12 U.S.C. 5365(i)(2)(A).

[3] 12 U.S.C. 5301(12).

[4] 12 U.S.C. 5365(i)(2)(C).

[5] 12 U.S.C. 5365(i)(2)(B).

[6] 77 FR 62417 (October 15, 2012).

[7] 77 FR 52718 (August 30, 2012) and 77 FR 70435 (November 26, 2012).

[8] 78 FR 55340 (September 10, 2013).

[9] 79 FR 20754 (April 14, 2014).

[10] 79 FR 58780 (September 30, 2014).

schedule RC–R of the Reports of Condition and Income (''Call Report''), the definitions of the items on schedule A.1.d (Capital) have been modified to refer to or mirror the definitions that appear on the Call Report. Furthermore, in order to ensure comparability among respondents and that transition provisions are being accurately and consistently applied, respondents would be required to apply the appropriate transition provisions to all transition-affected items of schedule A.1.d per the revised regulatory capital rule. With regard to the RWA sub-schedules, the standardized approach RWA and market RWA items of schedule A.1.c.1 (General RWA) have been changed in accordance with modifications to schedule RC–R of the Call Report that are currently being considered, and moved to a separate schedule A.1.c.2 (Standardized RWA). These changes include both the modification and addition of items, for an overall addition of 12 items. Additionally, the computed items one through five of the current sub-schedule A.1.c.2 (Advanced RWA) would be removed. Despite the alignment of these schedules with the Call Report, the column of actual values has not been removed because the values reported on these schedules are assumed to have completed the transition schedule outlined in the Revised Capital Framework, whereas values reported on the Call Report follow the transition schedule.

Revisions to Retail Repurchase Sub-Schedule

Due to recent activity by respondents involving settlements related to their representation & warranty (''R&W'') liabilities, additional detail would be collected about the R&W liabilities. Specifically, items would be added that collect the unpaid principal balance (''UPB'') of loans covered by completed settlements for which liability remains and for which no liability remains by vintage beginning with 2004, as well as total settlement across vintages, for the following categories of loans: loans sold to Fannie Mae, loans sold to Freddie Mac, loans insured by the U.S. government, loans securitized with monoline insurance, loans secured without monoline insurance, and whole loans sold.

Revisions to Securities Sub-Schedule

Because covered bonds are a material exposure to companies that have unique characteristics relative to other asset categories currently on this sub-schedule, the FDIC would add a covered bond category to sub-schedules A.3.b, A.3.c, A.3.d, and A.3.e in order to appropriately and separately evaluate respondents' projections of these assets. Additionally, two columns would be added to collect information for each of the asset categories of sub-schedule A.3.d that would allow changes in market value to be distinguished from changes in portfolio allocation for each projected quarter: (1) Beginning Fair Market Value, and (2) Fair Value Rate of Change, which is the weighted average percent change in fair value over the quarter. Finally, to reduce reporting burden and increase efficiency in reporting, the nine sub-asset categories of Domestic Non-Agency Residential Mortgage-Backed Securities (''RMBS'') would be removed from the same sub-schedules, and the AFS and HTM portions of sub-schedule A.3.c would be combined into an additional column to identify AFS amounts versus HTM amounts.

Revisions to Trading Sub-Schedule

Because credit valuation adjustment (''CVA'') losses are modeled separately from trading portfolio losses, the FDIC proposes that the profit (loss) amount related to CVA hedges be reported separately from other trading activity in the trading sub-schedule.

Revisions to Counterparty Risk Sub-Schedule

In order to allow respondents to use alternative methodologies for estimating losses related to the default of issuers and counterparties, the requirement of using the incremental default risk (''IDR'') methodology would be removed. Accordingly, items 1, 1a and 1b (Trading Incremental Default Losses, Trading Incremental Default Losses from securitized products, and Trading Incremental Default Losses from other credit sensitive instruments) would be modified to be Trading Issuer Default Losses. Additionally, items 3 (Counterparty Incremental Default Losses) and 3a (Impact of CCR IDR Hedges) would be removed, item 4 (Other CCR Losses) would be modified to be CCR Losses, and the item, Effect of CCR Hedges, would be added.

Regulatory Capital Instruments Schedule

Proposed changes to the Regulatory Capital Instruments Schedule would be responsive to industry feedback and ensure that information is being accurately captured. Specifically, the FDIC proposes (1) adding an item that collects employee stock compensation to the four quarterly redemption/repurchase and issuance activity sub-sections; (2) adding 18 items to the general risk-based capital rules section and 28 items to the revised regulatory capital section that collect activity other than issuances or repurchases for each instrument in the section, because respondents add this activity to other items; and (3) changing the capital balance items in the general risk-based capital rules section and the revised regulatory capital section from reported items to formulas, since they would be able to be computed using the items proposed above.

Regulatory Capital Transitions Schedule

Similar to the changes proposed to the RWA and Capital sub-schedules of the Summary Schedule, proposed changes to the Regulatory Capital Transitions Schedule would be made to better align the collection of regulatory capital components with modifications to schedule RC–R of the Call Report, which are currently being considered. The FDIC proposes (1) aligning the definitions of the items on the Capital Composition sub-schedule to be consistent with schedule RC–R; (2) modifying the RWA General sub-schedule to align with proposed revisions to schedule RC–R, including changing the name to Standardized RWA and modifying, removing, and adding items for a net increase of 15 items; (3) modifying, adding, and removing items of the Advanced RWA sub-schedule to align with sub-schedule A.1.c.2 (Advanced RWA on the Summary Schedule), for a net increase of 21 items; and (4) revising the Leverage Ratio sub-schedule in accordance with the supplementary leverage ratio rulemaking proposal, for a net increase of 10 items. Despite the alignment of these schedules with the Call Report, the column of actual values has not been removed because the values reported on these schedules are assumed to have completed the transition schedule outlined in the Revised Capital Framework, whereas values reported on the Call Report follow the transition schedule.

Operational Risk Schedule

Proposed changes to the Operational Risk Schedule would provide greater insight into the types and frequency of operational risk expenses incurred by respondents, which would improve ongoing supervisory activities.

The FDIC proposes adding a data item for respondents to voluntarily disclose how much of their mortgage related litigation reserve is attributable to contractual representation and warranty claims.

Counterparty Credit Risk Schedule

Significant additions would be made to the Counterparty Credit Risk Schedule in order to more adequately and accurately capture exposure information related to derivatives and securities financing transactions (''SFTs''). These additions would remediate deficiencies discovered in the current collection related to exposure, including a lack of information regarding collateral, asset types, and total exposure to a given counterparty, and have been carefully evaluated internally and vetted with respondents.

The FDIC proposes: (1) Adding a sub-schedule that collects the derivative exposures at a legal-entity netting-agreement level for the top 25 non-central clearing counterparty (''non-CCP'') and non-G–7 counterparties, as well as all CCPs and the G–7 counterparties, that includes a breakout of collateral into cash and non-cash, and exposures into 14 asset categories; (2) changing the current SFT sub-schedule to collect exposures and collateral separately at a counterparty legal-entity netting-agreement level for the top 25 non-CCP and non-G–7 counterparties, as well as all CCPs and the G–7 counterparties, and adding asset sub-categories for a total of 30 specific asset types; (3) removing all columns with the institution specification of margin period of risk (''MPOR'') under the global market shocks from sub-schedules F.1.a through F.1.e and F.2; (4) removing the column LGD Derived from Unstressed PD on F.2; and (5) adding columns to worksheet F.1.e to collect both gross and net stressed and unstressed current exposure to central clearing counterparties.

Burden Estimates

The FDIC estimates the burden of this collection as follows:

Current

Number of Respondents: 4.
Annual Burden per Respondent: 1,040.
Total Annual Burden: 4,160.

Proposed

Estimated Number of Respondents: 4.
Annual Burden per Respondent: 1,040.
Estimated Total Annual Burden: 4,160 hours.

The FDIC recognizes that the Board has estimated 88,401 hours for bank holding companies to prepare the Summary, Macroscenario, Operational risk, Regulatory capital transitions, Regulatory capital instruments, and Counterparty credit risk schedules submitted for the FR Y–14A. The FDIC believes that the systems covered institutions use to prepare the FR Y–14A reporting templates will also be used to prepare the reporting templates described in this notice. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the FDIC, including whether the information has practical utility;

(b) The accuracy of the FDIC'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 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.

Dated at Washington, DC, this 11th day of December.

Robert E. Feldman,

Executive Secretary, Federal Deposit Insurance Corporation.

[FR Doc. 2014–29418 Filed 12–16–14; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 12, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Brookfield Financial Holdings, Inc.,* Brookfield, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank of Brookfield, Brookfield, Illinois.

B. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Border Bancshares Inc.,* Greenbush, Minnesota; to acquire 100 percent of the voting shares of First Advantage Bank, Coon Rapids, Minnesota.

2. *Park Financial Group, Inc.,* Minneapolis, Minnesota; to become a bank holding company by acquiring 100 percent of the voting shares of Park State Bank, Duluth, Minnesota.

Board of Governors of the Federal Reserve System, December 12, 2014.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2014–29521 Filed 12–16–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–0932]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600

Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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. Written comments should be received within 60 days of this notice.

Proposed Project

Data Collection for Evaluation of Education, Communication, and Training Activities—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine (DGMQ) is requesting a revision of a currently approved generic clearance to conduct evaluation research. This will help CDC plan and implement health communication, education, and training activities to improve health and prevent the spread of disease. These activities include communicating with international travelers and other mobile populations, training healthcare providers, and educating public health departments and other federal partners.

The information collection for which the revision is sought is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This mission is supported by delegated legal authorities outlined in the Public Health Service (PHS) Act (42 U.S.C. 264) and in regulations that are codified in 42 Code of Federal Regulations (CFR) parts 70 and 71, and 34.

Since receiving initial approval for this generic, CDC has conducted three information collections. These information collections were in support of an Evaluation of Adapted Health Education Materials for LEP Spanish Speakers and Indigenous Migrants; Evaluation of the TravAlert Electronic Messaging System; and, a project entitled Scan This: Effectiveness of Quick Response Codes for Engaging International Panel Physicians. In order, these projects evaluated materials designed for specific audiences to determine if CDC's methods for communicating key public health messages were translated appropriately for low-English proficiency residents in the United States, were effective in reaching travelers in airports, and were useful in making CDC's immigration medical exam technical instructions more accessible.

Approval of this revision of the generic information collection will allow DGMQ continue to collect in an expedited manner information about the knowledge, attitudes, and behaviors of key audiences (such as refugees, immigrants, migrants, international travelers, travel industry partners, healthcare providers, non-profit agencies, customs brokers and forwarders, schools, state and local health departments) to help improve and inform these activities during both routine and emergency public health events. This generic OMB clearance will help DGMQ continue to refine these efforts in a timely manner, and will be especially valuable for communication activities that must occur quickly in response to public health emergencies.

DGMQ staff will use a variety of data collection methods for this proposed project: Interviews, focus groups, surveys, and pre/post-tests. Depending on the research questions and audiences involved, data may be gathered in-person, by telephone, online, or using some combination of these formats. Data may be collected in quantitative and/or qualitative forms. Numerous audience variables will be assessed under the auspices of this generic OMB clearance. These include, but are not limited to, knowledge, attitudes, beliefs, behavioral intentions, practices, behaviors, skills, self-efficacy, and information needs and sources. Insights gained from evaluation research will assist in the development, refinement, implementation, and demonstration of outcomes and impact of communication, education, and training activities.

DGMQ estimates that 17,500 respondents and 7,982 hours of burden will be involved in evaluation research activities each year. The information being collected will not impose a cost burden on the respondents beyond that associated with their time to provide the required data.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General Public	Focus Groups Screening form	1,050	1	10/60	175
Healthcare Professionals	Focus Groups Screening form	450	1	10/60	75
General Public	Focus Groups	525	1	90/60	788
Healthcare Professionals	Focus Groups	225	1	90/60	338
General Public	Interview Screening Form	700	1	10/60	117
Healthcare Professionals	Interview Screening Form	300	1	10/60	50
General Public	Interviews	350	1	1	350
Healthcare Professionals Interviews	Interviews	150	1	1	150
General Public	Survey Screening Forms	5,250	1	10/60	875

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Healthcare Professionals	Survey Screening Forms	2,250	1	10/60	375
General Public	Surveys	2,625	1	45/60	1,969
Healthcare Professionals	Surveys	1,125	1	45/60	844
General Public	Pre/Post Tests	1,750	1	45/60	1,313
Healthcare Professionals	Pre/Post Tests	750	1	45/60	563
TOTAL		17,500			7,982

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. 2014–29503 Filed 12–16–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Office for State, Tribal, Local and Territorial Support (OSTLTS) Meeting

In accordance with Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Governments, CDC/Agency for Toxic Substances and Disease Registry (ATSDR), announces the following meeting and Tribal Consultation Session:

Name: Tribal Advisory Committee (TAC) Meeting and 12th Biannual Tribal Consultation Session

Times and Dates:

8:00 a.m.–5:00 p.m., February 10, 2015 (TAC Meeting)

8:00 a.m.–5:00 p.m., February 11, 2015 (12th Biannual Tribal Consultation Session)

Place: The TAC Meeting and Tribal Consultation Session will be held at CDC Headquarters, 1600 Clifton Road, NE., Global Communications Center, Auditorium B3, Atlanta, Georgia 30333.

Status: The meetings are being hosted by CDC/ATSDR in-person only and are open to the public. Attendees must pre-register for the event by Friday, January 23, 2015, at the following link: *http://www.cdc.gov/tribal/meetings.html.*

Purpose: The purpose of these recurring meetings is to advance CDC/ATSDR support for and collaboration with tribes, and to improve the health of tribes through, including but not limited to, assisting in eliminating the health disparities faced by Indian Tribes, ensuring that access to critical health and human services and public health services is maximized to advance or enhance the social, physical, and economic status of Indians; and promoting health equity for all Indian people and communities. To advance these goals, CDC/ATSDR conducts government-to-government consultations with elected tribal officials or their authorized representatives. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding and comprehension.

Matters for Discussion: The TAC and CDC leaders will discuss the following public health issue topics: Native specimens, injury prevention and occupational safety, hepatitis C virus, tuberculosis, and communication and engagement with tribes; however, discussion is not limited to these topics.

During the 12th Biannual Tribal Consultation Session, tribes and CDC leaders will engage in a listening session with CDC's director and roundtable discussions with CDC senior leaders, and tribes will have an opportunity to present testimony on tribal health issues.

Tribal leaders are encouraged to submit written testimony by January 23, 2015, to April R. Taylor, Public Health Analyst for the Tribal Support Unit, OSTLTS, via mail to 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341 or email to *TribalSupport@cdc.gov.*

Depending on the time available, it may be necessary to limit the time of each presenter.

The agenda is subject to change as priorities dictate.

Information about the TAC, CDC's Tribal Consultation Policy, and previous meetings can be found at the following web link: *http://www.cdc.gov/tribal.*

Contact person for more information: April R. Taylor, Public Health Analyst, CDC/OSTLTS, 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341; email: *ARTaylor@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–29489 Filed 12–16–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Occupational Safety and Health Training Project Grants, PAR10–288, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates:

6:00 p.m.–8:00 p.m., January 13, 2015 (Closed)

8:00 a.m.–8:00 p.m., January 14, 2015 (Closed)

Place: Atlanta Airport Marriott, 4711 Best Road, Atlanta, Georgia 30337, Telephone: (404) 766–7900

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Occupational Safety and Health Training Project Grants, PAR10–288, initial review.''

Contact Person for More Information: Donald Blackman, Ph.D., Scientific Review Officer, CDC, 2400 Century Center Parkway, NE., 4th Floor, Room 4204, Mailstop E–74, Atlanta, Georgia 30345, *Telephone:* (404) 498–6185, *DYB7@CDC.GOV.*

The Director, Management Analysis and Services Office, has been delegated the

authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–29488 Filed 12–16–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC); Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 11:00 a.m.–1:00 p.m. (EST), January 13, 2015.

Place: This meeting will be held by teleconference.

Status: Open to the public, limited only by the availability of telephone ports. The public is welcome to participate during the public comment period, tentatively scheduled from 12:45 p.m. until 12:50 p.m.

To participate in the teleconference, please dial (877) 930–8819 and enter code 1579739.

Purpose: The Advisory Committee to the Director, CDC, shall advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The committee recommends ways to prioritize CDC's activities, improve results, and address health disparities. It also provides guidance to help CDC work more effectively with its various private and public sector constituents to make health protection a practical reality.

Matters for Discussion: The Advisory Committee to the Director will receive updates from the State, Tribal, Local and Territorial Subcommittee; the External Laboratory Safety Workgroup, and the Public Health—Health Care Collaboration Workgroup; and an update from the CDC Director on the Ebola response.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Carmen Villar, MSW, Designated Federal Officer, ACD, CDC, 1600 Clifton Road NE., M/S D–14, Atlanta, Georgia 30333; Telephone (404) 639–7158; Email: *GHickman@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2014–29487 Filed 12–16–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2033]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey entitled ''Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types (2015–2025).''

DATES: Submit either electronic or written comments on the collection of information by February 17, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2015–2025) (OMB Control Number 0910–NEW)

I. Background

From 1998–2008, FDA's National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected by FDA Specialists in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,
- Inadequate Cooking,

• Improper Holding/Time and Temperature and

• Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods (1998, 2003, and 2008) (Refs. 1–3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

Using this 10-year survey as a foundation, in 2013–2014, FDA initiated a new study in full service and fast food restaurants. This study will span 10 years with additional data collections planned for 2017–2018 and 2021–2022. FDA is proposing to collect data in select institutional foodservice and retail food store facility types in 2015–2016. This proposed study will also span 10 years with additional data collections planned for 2019–2020 and 2023–2024.

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Healthcare Facilities	Hospitals and long-term care facilities foodservice operations that prepare meals for highly susceptible populations as defined as follows: • Hospitals—A foodservice operation that provides for the nutritional needs of inpatients by preparing meals and transporting them to the patient's room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors). • Long-term care facilities—A foodservice operation that prepares meals for the residents in a group care living setting such as nursing homes and assisted living facilities. NOTE: For the purposes of this study, healthcare facilities that do not prepare or serve food to a highly susceptible population, such as mental healthcare facilities, are not included in this facility type category.
Schools (K–12)	Foodservice operations that have the primary function of preparing and serving meals for students in one or more grade levels from Kindergarten through Grade 12. A school foodservice may be part of a public or private institution.
Retail Food Stores	Supermarkets and grocery stores that have a deli department/operation as described as follows: • Deli department/operation—Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared on-site or received from a commissary in bulk containers, portioned, and displayed. Parts of deli operations may include: • Salad bars, pizza stations, and other food bars managed by the deli department manager. • Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager. Data will also be collected in the following areas of a supermarket or grocery store, if present: • Meat and seafood department/operation—Areas in a retail food store where raw animal food products, such as beef, pork, poultry, or seafood, are cut, prepared, stored, or displayed for sale to the consumer. • Produce department/operation—Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are managed by the produce manager.

The purpose of the study is to:

• Assist FDA with developing retail food safety initiatives and policies focused on the control of foodborne illness risk factors;

• Identify retail food safety work plan priorities and allocate resources to enhance retail food safety nationwide;

• Track changes in the occurrence of foodborne illness risk factors in retail and foodservice establishments over time; and

• Inform recommendations to the retail and foodservice industry and state, local, tribal, and territorial regulatory professionals on reducing the occurrence of foodborne illness risk factors.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (42 U.S.C. 243, Section 311(a)). Responsibility for carrying out the provisions of the Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq)* and the Economy Act (31 U.S.C. 1535) require FDA to provide assistance to other Federal, state, and local government bodies.

The objectives of the study are to:

• Identify the foodborne illness risk factors that are in most need of priority attention during each data collection period;

• Track trends in the occurrence of foodborne illness risk factors over time;

• Examine potential correlations between operational characteristics of food establishments and the control of foodborne illness risk factors;

• Examine potential correlations between elements within regulatory retail food protection programs and the control of foodborne illness risk factors; and

• Evaluate the impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

The methodology to be used for this information collection is described as follows. In order to obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each facility type. This sample size has been calculated to provide for sufficient observations to be 95 percent confident that the compliance percentage is within 5 percent of the true compliance percentage.

A geographical information system database containing a listing of businesses throughout the United States will be used as the establishment inventory for the data collections. FDA will sample establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low risk food preparation activities. The *FDA Food Code* contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation (Ref. 5). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who will serve as the data collectors for the 10-year study. The Specialists are

geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's Center for Food Safety and Applied Nutrition personnel in the application and interpretation of the *FDA Food Code* (Ref. 5).

Sampling zones will be established which are equal to the 150 mile radius around a Specialist's home location. The sample will be selected randomly from among all eligible establishments located within these sampling zones. The Specialists are generally located in major metropolitan areas (*i.e.* population centers) across the contiguous United States. Population centers usually contain a large concentration of the establishments FDA intends to sample. Sampling from the 150 mile radius sampling zones around the Specialists' home locations provides three advantages to the study:

1. It provides a cross section of urban and rural areas from which to sample the eligible establishments.
2. It represents a mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments.
3. It reduces overnight travel and therefore reduces travel costs incurred by the Agency to collect data.

The sample for each data collection period will be evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments will be selected for each Specialist for cases where the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists will contact the state or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist will verify with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist will also ascertain whether the selected facility is under legal notice from the state or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection, and a substitute establishment will be used. An invitation will be extended to the state or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form will be used by the Specialists during each data collection. The form is divided into three sections: Section 1—''Establishment Information;'' Section 2—''Regulatory Authority Information;'' and Section 3—''Foodborne Illness Risk Factor and Food Safety Management System Assessment.'' The information in Section 1—''Establishment Information'' of the form will be obtained during an interview with the establishment owner or person in charge by the Specialist and will include a standard set of questions.

The information in Section 2—''Regulatory Authority Information'' will be obtained during an interview with the program director of the state or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment. Section 3 includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management being implemented by the facility; and Part C for assessing the frequency and extent of food employee hand washing. The information in Part A will be collected from the Specialists' direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B will be collected by making direct observations and asking follow up questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C will be collected by making direct observations of food employee hand washing. No questions will be asked in the completion of Section 3, Part C of the form.

FDA will collect the following information associated with the establishment's identity: Establishment name, street address, city, state, zip code, county, industry segment, and facility type. The establishment identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, will also be collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA is working with the National Center for Food Protection and Defense to develop a Web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. Once developed, this platform will be accessible to state, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. FDA is currently transitioning from the manual entry of data to the use of hand-held technology. Contingent upon the completion of the Web-based platform, FDA intends to pilot test the use of hand-held technology during its 2015–2016 risk factor study data collection in institutional foodservice and retail food store facility types, with the goal to have it fully implemented by the next the data collection in restaurant facility types that will occur in 2017–2018. When a data collector is assigned a specific establishment, he or she will conduct the data collection and enter the information into the Web-based data platform. The interface will support the manual entering of data, as well as the ability to upload a fillable PDF.

The burden for this collection of information is as follows. For each data collection, the respondents will include: (1) The person in charge of the selected facility type (whether it be a healthcare facility, school, or supermarket/grocery store); and (2) the program director (or designated individual) of the respective regulatory authority. In order to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that 400 data collections will be required in each of the three facility types. Therefore, the total number of responses will be 2,400 (400 data collections $\times$ 3 facility types $\times$ 2 respondents per data collection).

The burden associated with the completion of Sections 1 and 3 of the form is specific to the persons in charge of the selected facilities. It includes the time it will take the persons in charge to accompany the data collectors during the site visit and answer the data collectors' questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities. It includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

To calculate the estimate of the hours per response, FDA will use the average data collection duration for similar facility types during FDA's 2008 Risk Factor Study (Ref. 3) plus an extra 30 minutes (0.5 hours) for the information collection related to Section 3, Part B of

the form. FDA estimates that it will take the persons in charge of healthcare facility types, schools, and retail food stores 150 minutes (2.5 hours), 120 minutes (2 hours), and 180 minutes (3 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. The total burden estimate for a data collection, including both the program director's and the person in charge's responses, in healthcare facility types is 180 minutes (150+30)(3 hours), in schools is 150 minutes (120+30)(2.5 hours), and in retail food stores is 210 minutes (180+30)(3.5 hours).

Based on the number of entry refusals from the 2013–2014 Risk Factor Study in the restaurant facility types, we estimate a refusal rate of 2 percent in the institutional foodservice and retail food store facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2015–2016 Data Collection (Healthcare Facilities)—Completion of Sections 1 and 3	400	1	400				2.5	1,000
2015–2016 Data Collection (Schools)—Completion of Sections 1 and 3	400	1	400				2	800
2015–2016 Data Collection (Retail Food Stores)—Completion of Sections 1 and 3	400	1	400				3	1,200
2015–2016 Data Collection-Completion of Section 2—All Facility Types	1,200	1	1,200				0.5	600
2017–2018 Data Collection-Entry Refusals—All Facility Types				24	1	24	[2] 0.08	1.92
Total Hours								3,601.92

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] (5 minutes.)

II. References

The following reference has 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://regulations.gov*.

1. ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123546.pdf*.
2. ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).'' Available at: *http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf*
3. ''FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224682.pdf*.
4. FDA National Retail Food Team. ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' Available at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224152.pdf*.
5. FDA Food Code. Available at: *http://www.fda.gov/FoodCode*.

Dated: December 8, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29478 Filed 12–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from

the public during the review and approval period.

DATES: Comments on this ICR should be received no later than January 16, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Competitive Grant Final Report

OMB No.: 0915–0356—NEW

Abstract: On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA), Section 2951 of the ACA amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant and Early Childhood Home Visiting Program (MIECHV) (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). (The MIECHV program was reauthorized by the Protecting Access to Medicare Act of 2014 (Pub. L.113–93).) The MIECHV program responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the federal, state, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs. Under this program, competitive funding has been awarded since June 2011 for Competitive Development Grants and Competitive Expansion Grants. Competitive Development Grants support the efforts of states and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, in order to develop the infrastructure and capacity needed to seek a Competitive Expansion Grant in the future. Competitive Expansion Grants support the efforts of states and jurisdictions that had already made significant progress towards a high quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system.

Since federal fiscal year 2011, 19 states have been awarded Competitive Development Grants, and 37 states have been awarded Competitive Expansion Grants. Grantees of the Competitive Grant Program need to complete final reports in order to comply with HRSA reporting requirements. Grantees that were awarded Competitive Development Grants during federal fiscal year 2011 were eligible for Competitive Expansion Grants in federal fiscal year 2013. For this reason, some grantees have been awarded up to two Competitive Grants to date. Ten grantees have both a Competitive Development Grant and a Competitive Expansion Grant. Additional funds are being made available for Competitive Grants in federal fiscal year 2015. Up to 35 grants are anticipated to be awarded on March 1, 2015, with a project period equal to 2 years and 7 months. Grantees are expected to use 2015 competitive grant funds to provide ongoing support to high-quality evidence-based home visiting programs and for the development and expansion of evidence-based home visiting programs funded, in whole or in part, by the MIECHV program through increased enrollment and retention of families served. After Competitive Grant issuance in 2015, some MIECHV grantees may have up to three competitive grants for which final reports need to be submitted. HRSA is collecting information from MIECHV grantees that have received competitive grant funds as part of the agency's final reporting requirements. The final report will be completed by grantees funded under the Competitive Grant Program and submitted to HRSA within 90 days of the project period end date. The burden estimates presented in the table below are based on consultations with states on the final reporting requirements described in the competitive grant guidance documents.

Need and Proposed Use of the Information: Submission of a final report is a reporting requirement under the grant award. The final report will enable assessment of program effectiveness and impact on the health and development of service recipients. Final reports will be assessed to measure and quantify the degree to which each grantee was successful in implementing the grant and ensuring yearly program improvement. Data will be extracted from final reports and aggregated, using suitable analytic approaches, to compare, contrast, and identify successes, areas for improvement, and promising practices across the program. These findings will be used to identify the accomplishments of the MIECHV program, support program or grantee improvement, and craft or inform dissemination strategies.

Likely Respondents: MIECHV grantees that have received a competitive (D89) grant award.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total Burden Hours
MIECHV Competitive Grant Final Report—Fiscal Year 2011 and 2012 Development Grantees	19	1	19	25	475
MIECHV Competitive Grant Final Report—Fiscal Year 2011, 2012, 2013, and 2014 Expansion Grantees	37	1	37	25	925
MIECHV Competitive Grant Final Report—Fiscal Year 2015 Expansion Grantees	35	1	35	25	875

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total Burden Hours
Total	44				2275

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–29520 Filed 12–16–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than January 16, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Bureau of Primary Health Care (BPHC) Uniform Data System.

OMB No.: 0915–0193—Revision.

Abstract: The Uniform Data System (UDS) is the Bureau of Primary Health Care's (BPHC's) annual reporting system for HRSA-supported health centers. The UDS includes reporting requirements for Health Center Program grantees and look-alikes of the following programs: the Community Health Center program, the Migrant Health Center program, the Health Care for the Homeless program, and the Public Housing Primary Care program.

Need and Proposed Use of the Information: HRSA collects UDS data which are used to ensure compliance with legislative and regulatory requirements, improve health center performance and operations, and report overall program accomplishments. The data help to identify trends over time, enabling HRSA to establish or expand targeted programs and identify effective services and interventions to improve the health of underserved communities and vulnerable populations. UDS data are compared with national health-related data, including the National Health Interview Survey and the National Health and Nutrition Examination Survey, to review differences between the health center patient populations and the U.S. population at large and those individuals and families who rely on the health care safety net for primary care. UDS data also inform Health Center Programs, partners, and communities about the patients served by health centers. To meet these objectives, BPHC requires a core set of data collected annually. The UDS data collection for 2015 will be revised in three ways. A new line will be added to identify patients that are dually eligible for Medicare and Medicaid, a new measure will be added to collect the number of children with dental sealants on their first molar tooth, and the existing diabetes clinical measure will be streamlined to align with the National Quality Forum (NQF) endorsed measure and Healthy People 2020 national benchmark. Specifically, health centers will no longer report three categories: Hba1c less than 8%; Hba1c greater than or equal to 8% and less than or equal to 9%; and Hba1c greater than 9%. Health centers will report two categories: Hba1c less than 8% and Hba1c greater than 9%.

Likely Respondents: The respondents will be HRSA BPHC Health Center Program grantees and look-alikes.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Universal Report	1,302	1	1302	170	221,340
Grant Report	499	1	499	22	10,978
Total	1,801			192	232,318

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–29505 Filed 12–16–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than February 17, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Voluntary Partner Surveys to Implement Executive Order 12862 in the Health Resources and Services Administration OMB No. 0915–0212—Extension

Abstract: In response to Executive Order 12862, the Health Resources and Services Administration (HRSA) is proposing to conduct voluntary customer surveys of its partners to assess strengths and weaknesses in program services and processes. HRSA partners are typically state or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting a generic approval from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees, to measure satisfaction with the training experience. Results of these surveys will be used to plan and redirect resources and efforts as needed to improve services and processes.

Focus groups may also be used to gain partner input into the design of mail and telephone surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred data collection methods.

A generic approval allows HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If generic approval is approved, information on each individual partner survey will not be published in the **Federal Register**.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
In-class evaluations	40,000	1	40,000	.05	2,000
Mail/Telephone surveys	12,000	1	12,000	.25	3,000
Focus groups	250	1	250	1.5	375
Total	52,250	1	52,250	.103	5,375

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–29504 Filed 12–16–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and

Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 79 FR 69499 dated November 21, 2014).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of Rural Health Policy. Specifically, this notice: (1) Changes the name from the Office of Rural Health Policy to the Federal Office of Rural Health Policy; (2) establishes the Policy Research Division (RH5); (2) establishes the Administrative Operations Division (RH6); and (3) abolishes the Border Health Division.

Chapter RH—Federal Office of Rural Health Policy

Section RH–00, Mission

To improve access to quality health care in rural communities.

Section RH–10, Organization

Delete the organization for the Office of Rural Health Policy (RH) in its entirety and replace with the following:

The Federal Office of Rural Health Policy (RH) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Federal Office of Rural Health Policy includes the following components:

(1) Office of the Associate Administrator (RH);

(2) Hospital State Division (RH1);

(3) Community-Based Division (RH2);

(4) Office for the Advancement of Telehealth (RH4);

(5) Policy Research Division (RH5); and

(6) Administrative Operations Division (RH6).

Section RH–20, Functions

(1) Establish the Policy Research Division (RH5) and transfer the policy research functions from the Office of the Associate Administrator (RH) to the newly established Policy Research Division (RH5); (2) establish the Administrative Operations Division (RH6) and transfer the administrative operations functions from the Office of the Associate Administrator (RH) to the newly established Administrative Operations Division (RH6); (3) transfer the functions of the Border Health Division (RH3) to the Office of the Associate Administrator (RH); (4) abolish the Border Health Division; and (5) update the functional statement for the Office of Associate Administrator (RH).

Office of the Associate Administrator (RH)

The Federal Office of Rural Health Policy (FORHP) is responsible for the overall leadership and management of the office. FORHP serves as a focal point within the Department of Health and Human Services (HHS) for rural health-related issues and as a principal source of advice to the Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the nation's rural areas. FORHP provides leadership within HHS and with stakeholders in providing information and counsel related to access to, and financing and quality of, health care to rural populations. Specifically, the Office of the Associate Administrator: (1) Provides staff support to the National Advisory Committee on Rural Health and Human Services; (2) stimulates and coordinates interaction on rural health activities and programs in the Agency, Department and with other federal agencies; (3) establishes and maintains a resource center for the collection and dissemination of the latest information and research findings related to the delivery of health services in rural areas; (4) ensures successful dissemination of appropriate information technology advances, such as electronic health records systems; (5) monitors the health information technology policy and activities of other HHS components for useful application in rural areas; (6) monitors HRSA's border health activities and investments to promote collaboration and improve health care access to those living along the U.S.-Mexico border; (7) provides overall direction and leadership over the management of nationwide community-based rural health grants programs; (8) provides overall direction and leadership over the management of a program of state grants which support collaboration within state offices of rural health; (9) provides overall direction and leadership over the management of programs to advance the use of telehealth and coordination health information technology; and (10) provides overall direction and leadership over the office's administrative and management functions.

Policy Research Division (RH5)

The Policy Research Division serves as the focal point within FORHP to support health policy and research focused on rural populations. Specifically, the Policy Research Division: (1) Supports rural health research centers and keeps informed of research and demonstration projects funded by states and foundations in the field of rural health care delivery; (2) establishes and maintains a resource center for the collection and dissemination of the latest information and research findings related to the delivery of health services in rural areas; (3) maintains data and analytic capabilities to support office functions; (4) advises the Agency, Administrator, and Department on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in the programs established under titles XVIII and XIX of the Social Security Act, on the financial viability of small rural hospitals and the ability of rural areas to attract and retain physicians and other health professionals; and (5) monitors rural hospital impact analyses developed by the Centers for Medicare and Medicaid Services whenever proposed regulations might have a significant impact on a substantial number of small rural hospitals.

Administrative Operations Division (RH6)

The Administrative Operations Division collaborates with FORHP leadership to plan, coordinate, and direct FORHP-wide administrative management activities. Specifically, the Administrative Operations Division: (1) Develops, executes, and monitors FORHP's budget; (2) provides guidance and coordination of human resources; (3) plans, coordinates, and manages FORHP's grant activities; (4) plans, coordinates, and manages FORHP's procurement activities; (5) coordinates the review and clearance of correspondence and official documents to and from FORHP; and (6) provides additional management support services including, but not limited to, timekeeping, supplies, equipment, space, records, and training.

Section RH–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: December 11, 2014.

Mary K. Wakefield,

Administrator.

[FR Doc. 2014–29576 Filed 12–16–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov*.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html*.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov*.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 31, 2014.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	*Community map repository*	Effective date of modification	Community No.
Alabama:					
Autauga (FEMA Docket No.: B–1428).	City of Prattville (14–04–4875P).	The Honorable Bill Gillespie, Jr., Mayor, City of Prattville, 101 West Main Street, Prattville, AL 36067.	Planning and Development Department, City Hall Annex, 102 West Main Street, Prattville, AL 36067.	September 22, 2014	010002
Autauga (FEMA Docket No.: B–1428).	City of Prattville (14–04–4876P).	The Honorable Bill Gillespie, Jr., Mayor, City of Prattville, 101 West Main Street, Prattville, AL 36067.	Planning and Development Department, City Hall Annex, 102 West Main Street, Prattville, AL 36067.	September 22, 2014	010002
Autauga (FEMA Docket No.: B–1428).	Unincorporated areas of Autauga County (14–04–4875P).	The Honorable Carl Johnson, Chairman, Autauga County Board of Commissioners, 135 North Court Street, Suite B, Prattville, AL 36067.	Autauga County Emergency Management Agency, 826 Gillespie Street, Prattville, AL 36067.	September 22, 2014	010314
Autauga (FEMA Docket No.: B–1428).	Unincorporated areas of Autauga County (14–04–4876P).	The Honorable Carl Johnson, Chairman, Autauga County Board of Commissioners, 135 North Court Street, Suite B, Prattville, AL 36067.	Autauga County Emergency Management Agency, 826 Gillespie Street, Prattville, AL 36067.	September 22, 2014	010314
Houston (FEMA Docket No.: B–1423).	City of Dothan (14–04–2072P).	The Honorable Mike Schmitz, Mayor, City of Dothan, P.O. Box 2128, Dothan, AL 36302.	Engineering Department, 126 North St. Andrews Street, Dothan, AL 36302.	September 11, 2014	010104
Arizona:					
Maricopa (FEMA Docket No.: B–1428).	Town of Buckeye (14–09–0978P).	The Honorable Jackie A. Meck, Mayor, Town of Buckeye, 530 East Monroe Avenue, Buckeye, AZ 85326.	Town Hall, 100 North Apache Street, Suite A, Buckeye, AZ 85326.	September 12, 2014	040039

State and county	Location and case No.	Chief executive officer of community	*Community map repository*	Effective date of modification	Community No.
Mohave (FEMA Docket No.: B–1423).	Unincorporated areas of Mohave County (14–09–0399P).	The Honorable Gary Watson, Chairman, Mohave County Board of the Supervisors, 700 West Beale Street, Kingman, AZ 86402.	Mohave County Planning Department, 700 West Beale Street, Kingman, AZ 86402.	August 29, 2014	040058
Pima (FEMA Docket No.: B–1428).	Unincorporated areas of Pima County (14–09–1215P).	The Honorable Sharon Bronson, Chair, Pima County Board of Supervisors, 130 West Congress Street, 11th Floor, Tucson, AZ 85701.	Pima County Flood Control District, 97 East Congress Street, 3rd Floor, Tucson, AZ 85701.	September 3, 2014	040073
Pinal (FEMA Docket No.: B–1428).	Unincorporated areas of Pinal County (13–09–1389P).	The Honorable Anthony Smith, Chairman, Pinal County Board of Supervisors, P.O. Box 827, Florence, AZ 85132.	Pinal County Engineering Department, 31 North Pinal Street, Building F, Florence, AZ 85232.	September 12, 2014	040077
Colorado:					
Adams (FEMA Docket No.: B–1423).	City of Thornton (14–08–0032P).	The Honorable Heidi Williams, Mayor, City of Thornton, 9500 Civic Center Drive, Thornton, CO 80229.	City Hall, 9500 Civic Center Drive, Thornton, CO 80229.	August 29, 2014	080007
Arapahoe (FEMA Docket No.: B–1423).	City of Centennial (13–08–1142P).	The Honorable Cathy Noon, Mayor, City of Centennial, 13133 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 76 Inverness Drive East, Suite A, Centennial, CO 80112.	September 5, 2014	080315
Arapahoe (FEMA Docket No.: B–1423).	Unincorporated areas of Arapahoe County (13–08–1142P).	The Honorable Nancy Doty, Chair, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, CO 80120.	Arapahoe County Public Works and Development Department, 6924 South Lima Street, Centennial, CO 80112.	September 5, 2014	080011
Douglas (FEMA Docket No.: B–1423).	Town of Castle Rock (13–08–1316P).	The Honorable Paul Donahue, Mayor, Town of Castle Rock, 100 North Wilcox Street, Castle Rock, CO 80104.	Utilities Department, 175 Kellogg Court, Castle Rock, CO 80109.	September 5, 2014	080050
Douglas (FEMA Docket No.: B–1423).	Unincorporated areas of Douglas County (13–08–1316P).	The Honorable Roger Partridge, Chairman, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Douglas County Public Works Department, 100 3rd Street, Castle Rock, CO 80104.	September 5, 2014	080049
Florida:					
Brevard (FEMA Docket No.: B–1423).	City of Cocoa Beach (13–04–8100P).	The Honorable Dave Netterstrom, Mayor, City of Cocoa Beach, 2 South Orlando Avenue, Cocoa Beach, FL 32931.	Building Department, 2 South Orlando Avenue, Cocoa Beach, FL 32931.	September 11, 2014	125097
Brevard (FEMA Docket No.: B–1423).	Unincorporated areas of Brevard County (13–04–8100P).	The Honorable Mary Bolin Lewis, Chair, Brevard County Board of Commissioners, 2725 Judge Fran Jamieson Way, Viera, FL 32940.	Brevard County Public Works Department, 2725 Judge Fran Jamieson Way, Viera, FL 32940.	September 11, 2014	125092
Manatee (FEMA Docket No.: B–1423).	City of Bradenton (14–04–1057P).	The Honorable Wayne H. Poston, Mayor, City of Bradenton, 101 Old Main Street, Bradenton, FL 34205.	City Hall, 101 Old Main Street, Bradenton, FL 34205.	August 29, 2014	120155
Monroe (FEMA Docket No.: B–1428).	City of Marathon (14–04–4871P).	The Honorable Dick Ramsay, Mayor, City of Marathon, 9805 Overseas Highway, Marathon, FL 33050.	Planning Department, 9805 Overseas Highway, Marathon, FL 33050.	September 12, 2014	120681
Orange (FEMA Docket No.: B–1435).	City of Orlando (14–04–3140P).	The Honorable Buddy Dyer, Mayor, City of Orlando, P.O. Box 4990, Orlando, FL 32802.	Permitting Services Department, 400 South Orange Avenue, Orlando, FL 32801.	September 5, 2014	120186
Osceola (FEMA Docket No.: B–1423).	Unincorporated areas of Osceola County (13–04–8297P).	The Honorable Fred Hawkins, Jr., Chairman, Osceola County Board of Commissioners, 1 Courthouse Square, Kissimmee, FL 34741.	Osceola County Stormwater Section, 1 Courthouse Square, Kissimmee, FL 34741.	September 5, 2014	120189
Sarasota (FEMA Docket No.: B–1423).	City of Sarasota (13–04–5178P).	The Honorable Shannon Snyder, Mayor, City of Sarasota, 1565 1st Street, Sarasota, FL 34236.	City Hall, 1565 1st Street, Sarasota, FL 34236.	August 29, 2014	125150
Seminole (FEMA Docket No.: B–1428).	Unincorporated areas of Seminole County (14–04–0226P).	The Honorable Bob Dallari, Chairman, Seminole County Board of Commissioners, 1101 East 1st Street, Sanford, FL 32771.	Building Division, 1101 East 1st Street, Sanford, FL 32771.	September 12, 2014	120289
Georgia:.					
Columbia (FEMA Docket No.: B–1423).	Unincorporated areas of Columbia County (14–04–3712P).	The Honorable Ron C. Cross, Chairman, Columbia County Board of Commissioners, P.O. Box 498, Evans, GA 30809.	Columbia County Planning Commission, 650–B Ronald Reagan Drive, Evans, GA 30809.	September 11, 2014	130059

State and county	Location and case No.	Chief executive officer of community	*Community map repository*	Effective date of modification	Community No.
Hawaii:.					
Hawaii (FEMA Docket No.: B–1428).	Hawaii County (13–09–2726P).	The Honorable William P. Kenoi, Mayor, Hawaii County, 25 Aupuni Street, Hilo, HI 96720.	Hawaii County Department of Public Works, 101 Pauahi Street, Suite 7, Hilo, HI 96720.	September 22, 2014	155166
Kansas:					
Johnson (FEMA Docket No.: B–1423).	City of Overland Park (13–07–2288P).	The Honorable Carl Gerlach, Mayor, City of Overland Park, 8500 Santa Fe Drive, Overland Park, KS 66212.	City Hall, 8500 Santa Fe Drive, Overland Park, KS 66212.	August 27, 2014	200174
Johnson (FEMA Docket No.: B–1423).	Unincorporated areas of Johnson County (13–07–2288P).	The Honorable Ed Eilert, Chairman, Johnson County Board of Commissioners, 111 South Cherry, Suite 3300, Olathe, KS 66061.	Johnson County Courthouse, Planning Office, 111 South Cherry, Suite 3500, Olathe, KS 66061.	August 27, 2014	200159
Montana:.					
Silver Bow (FEMA Docket No.: B–1423).	Unincorporated areas of Butte-Silver Bow County (13–08–1393P).	The Honorable Cindi Shaw, Chair, Butte-Silver Bow County Council of Commissioners, 155 West Granite Street, Butte, MT 59701.	Butte-Silver Bow County Floodplain Administrator, 155 West Granite Street, Butte, MT 59701.	August 29, 2014	300077
Nevada:					
Clark (FEMA Docket No.: B–1428).	Unincorporated areas of Clark County (14–09–0768P).	The Honorable Steve Sisolak, Chairman, Clark County Board of Commissioners, 500 South Grand Central Parkway, Las Vegas, NV 89155.	Clark County Public Works Department, 500 South Grand Central Parkway, Las Vegas, NV 89155.	September 10, 2014	320003
Washoe (FEMA Docket No.: B–1428).	City of Reno (14–09–0059P).	The Honorable Robert Cashell, Mayor, City of Reno, P.O. Box 1900, Reno, NV 89505.	City Hall, 450 Sinclair Street, Reno, NV 89501.	August 21, 2014	320020
North Carolina:					
Wake (FEMA Docket No.: B–1411).	Town of Cary (13–04–5160P).	The Honorable Harold Weinbrecht, Mayor, Town of Cary, P.O. Box 8005, Cary, NC 27512.	Town Hall, 316 North Academy Street, Cary, NC 27512.	May 29, 2014	370238
Wake (FEMA Docket No.: B–1411).	Town of Cary (13–04–5161P).	The Honorable Harold Weinbrecht, Mayor, Town of Cary, P.O. Box 8005, Cary, NC 27512.	Town Hall, 316 North Academy Street, Cary, NC 27512.	May 29, 2014	370238
Wake (FEMA Docket No.: B–1411).	Town of Cary (13–04–5162P).	The Honorable Harold Weinbrecht, Mayor, Town of Cary, P.O. Box 8005, Cary, NC 27512.	Town Hall, 316 North Academy Street, Cary, NC 27512.	May 29, 2014	370238
Wake (FEMA Docket No.: B–1411).	Town of Cary (13–04–5163P).	The Honorable Harold Weinbrecht, Mayor, Town of Cary, P.O. Box 8005, Cary, NC 27512.	Town Hall, 316 North Academy Street, Cary, NC 27512.	May 29, 2014	370238
Wake (FEMA Docket No.: B–1411).	Unincorporated areas of Wake County (13–04–5161P).	The Honorable Joe Bryan, Chairman, Wake County Board of Commissioners, P.O. Box 550, Raleigh, NC 27602.	Wake County Office Building, 336 Fayetteville Street, Raleigh, NC 27602.	May 29, 2014	370368
Wake (FEMA Docket No.: B–1411).	Unincorporated areas of Wake County (13–04–5943P).	The Honorable Joe Bryan, Chairman, Wake County Board of Commissioners, P.O. Box 550, Raleigh, NC 27602.	Wake County Office Building, 336 Fayetteville Street, Raleigh, NC 27602.	May 29, 2014	370368
North Dakota:					
Stark, (FEMA Docket No.:, B–1428).	City of Dickinson, (14–08–0354P).	The Honorable Dennis W. Johnson, Mayor, City of Dickinson, 99 2nd Street East, Dickinson, ND 58601.	Building Department, 99 2nd Street East, Dickinson, ND 58601.	September 5, 2014	380117
Stark (FEMA Docket No.: B–1428).	Unincorporated areas of Stark County (14–08–0354P).	The Honorable Russ Hoff, Chairman, Stark County Board of Commissioners, P.O. Box 130, Dickinson, ND 58602.	Stark County Recorder, 51 3rd Street East, Dickinson, ND 58602.	September 5, 2014	385369
South Carolina:					
Jasper (FEMA Docket No.: B–1428).	Town of Hardeeville (14–04–1941P).	The Honorable Bronco Bostick, Mayor, Town of Hardeeville, 205 East Main Street, Hardeeville, SC 29927.	City Hall, 205 Main Street, Hardeeville, SC 29927.	September 18, 2014	450113
Jasper (FEMA Docket No.: B–1428).	Unincorporated areas of Jasper County (14–04–1941P).	The Honorable Barbara Clark, Chair, Jasper County Council, P.O. Box 1149, Ridgeland, SC 29936.	Jasper County Planning Department, 358 3rd Avenue, Ridgeland, SC 29936.	September 18, 2014	450112
Richland (FEMA Docket No.: B–1428).	Unincorporated areas of Richland County (13–04–8158P).	The Honorable Norman Jackson, Chairman, Richland County Council, P.O. Box 90617, Columbia, SC 29209.	Richland County Courthouse, 1701 Main Street, Columbia, SC 29202.	September 15, 2014	450170
Utah:					

State and county	Location and case No.	Chief executive officer of community	*Community map repository*	Effective date of modification	Community No.
Salt Lake (FEMA Docket No.: B–1428).	City of West Jordan (13–08–1221P).	The Honorable Kim V. Rolfe, Mayor, City of West Jordan, 8000 South Redwood Road, West Jordan, UT 84088.	City Hall, 8000 South Redwood Road, West Jordan, UT 84088.	September 11, 2014	490108
Weber (FEMA Docket No.: B–1428).	City of Ogden (13–08–0663P).	The Honorable Mike Caldwell, Mayor, City of Ogden, 2549 Washington Boulevard, Ogden, UT 84401.	City Hall, 2549 Washington Boulevard, Ogden, UT 84401.	September 22, 2014	490189

[FR Doc. 2014–29563 Filed 12–16–14; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of January 7, 2014 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 24, 2014.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Montgomery County, Alabama, and Incorporated Areas Docket No.: FEMA–B–1351	
City of Montgomery	City Hall, 103 North Perry Street, Montgomery, AL 36104.
Town of Pike Road	Town Hall, 9575 Vaughn Road, Pike Road, AL 36064.
Unincorporated Areas of Montgomery County	Montgomery County Courthouse Annex 1, 100 South Lawrence Street, Montgomery, AL 36104.
Ventura, California, and Incorporated Areas Docket No.: FEMA–B–1351	
City of Camarillo	Public Works Department, 601 Carmen Drive, Camarillo, CA 93010.
Unincorporated Areas of Ventura County	Ventura County Hall of Administration, 800 South Victoria Avenue, Ventura, CA 93009.
Rush County, Indiana, and Incorporated Areas Docket No.: FEMA–B–1275	
City of Rushville	Rush County Courthouse, Area Plan Commission, Room 21, 101 East 2nd Street, Rushville, IN 46173.
Town of Carthage	Rush County Courthouse, Area Plan Commission, Room 211, 101 East 2nd Street, Rushville, IN 46173.

Community	Community map repository address
Unincorporated Areas of Rush County	Rush County Courthouse, Area Plan Commission, Room 211, 101 East 2nd Street, Rushville, IN 46173.

[FR Doc. 2014–29562 Filed 12–16–14; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4203–DR; Docket ID FEMA–2014–0003]

Arizona; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Arizona (FEMA–4203–DR), dated November 5, 2014, and related determinations.

DATES: *Effective Date:* November 5, 2014.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 5, 2014, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Arizona resulting from severe storms and flooding during the period of September 7–9, 2014, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Arizona.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Mark H. Landry, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Arizona have been designated as adversely affected by this major disaster:

La Paz and Maricopa Counties for Public Assistance.

All areas within the State of Arizona are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2014–29565 Filed 12–16–14; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0002; Internal Agency Docket No. FEMA–B–1451]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before March 17, 2015.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1451, to Luis

Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 24, 2014.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Grant Parish, Louisiana, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Town of Colfax	Town Hall, 1208 Main Street, Colfax, LA 71417.
Town of Montgomery	Town Hall, 625 Woodland Street, Montgomery, LA 71454.
Town of Pollock	Town Hall, 3813 Patterson Street, Pollock, LA 71467.
Unincorporated Areas of Grant Parish	Grant Parish Consolidated Gas Utility District Building, 506 Main Street, Colfax, LA 71454.
Village of Creola	Creola Village Hall, 241 Grays Creek Road, Dry Prong, LA 71423.
Village of Dry Prong	Village Hall, 607 Russell Hataway Drive, Dry Prong, LA 71423.
Village of Georgetown	Village Hall, 4418 Highway 500, Georgetown, LA 71432.
City of Hampton, Virginia (Independent City)	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
City of Hampton	Public Works Engineering, 22 Lincoln Street, Hampton, VA 23669.

[FR Doc. 2014–29560 Filed 12–16–14; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0008]

Agency Information Collection Activities: Biographic Information, Form G–325, G–325A, G–325B, and G–325C; Extension, Without Change, of a Currently Approved Collection

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until February 17, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0008 in the subject box, the agency name and Docket ID USCIS–2005–0024. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *www.regulations.gov* under e-Docket ID number USCIS–2005–0024;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Biographic Information.

(3) *Agency form numbers, if any, and the applicable component of the DHS sponsoring the collection:* G–325, G–325A, G–325B, and G–325C; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. These forms are used when it is necessary to check other agency records on applications or petitions submitted by applicants for certain benefits under the Immigration and Nationality Act (Act).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collections G–325 is 11,006 and the estimated hour burden per response is .25 hours. The estimated total number of respondents for the information collections G–325A is 565,180 and the estimated hour burden per response is .25 hours. The estimated total number of respondents for the information collections G–325B is 744,942 and the estimated hour burden per response is .25 hours. The estimated total number of respondents for the information collections G–325C is 100,000 and the estimated hour burden per response is .25 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,421,188 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* Any estimated total annual cost burden associated with this collection of information is reflected in the individual USCIS information collections that this collection supports.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: *http://www.regulations.gov.* We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377.

Dated: December 10, 2014.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014–29466 Filed 12–16–14; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2014–N222; FXES1113 0600000–156–FF06E00000]

Endangered and Threatened Wildlife and Plants; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered or threatened species. With some exceptions, the Endangered Species Act of 1973, as amended (Act), prohibits activities with endangered and threatened species unless a Federal permit allows such activity. The Act requires that we invite public comment before issuing these permits.

DATES: To ensure consideration, please send your written comments by January 16, 2015.

ADDRESSES: You may submit comments or requests for copies or more information by any of the following methods. Alternatively, you may use one of the following methods to request hard copies or a CD–ROM of the documents. Please specify the permit you are interested in by number (*e.g.,* Permit No. TE–XXXXXX).

- *Email: permitsR6ES@fws.gov.* Please refer to the respective permit number (*e.g.,* Permit No. TE–XXXXXX) in the subject line of the message.
- *U.S. Mail:* Ecological Services, U.S. Fish and Wildlife Service, P.O. Box 25486–DFC, Denver, CO 80225.
- *In-Person Drop-off, Viewing, or Pickup:* Call (303) 236–4212 to make an appointment during regular business hours at 134 Union Blvd., Suite 645, Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Kathy Konishi, Permit Coordinator, Ecological Services, (307) 772–2374 x 248 (phone); *permitsR6ES@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

The Act (16 U.S.C. 1531 *et seq.*) prohibits activities with endangered and threatened species unless a Federal permit allows such activity. Along with our implementing regulations at 50 CFR 17, the Act provides for permits and requires that we invite public comment before issuing these permits.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes the permittees to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of propagation or survival, or interstate commerce (the latter only in the event that it facilitates scientific purposes or enhancement of propagation or survival). Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, and Federal agencies and the public to comment on the following applications. Documents and other information the applicants have submitted with their applications are available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit Application Number TE49168B

Applicant: Catherine Ortega, Durango, CO.

The applicant requests a permit to conduct presence/absence surveys for the southwestern willow flycatcher (*Empidonax traillii extimus*) in Arizona, New Mexico, Utah, and Colorado for the purpose of enhancing the species' survival.

Permit Application Number TE50643B

Applicant: Vaughn Weaver, Wichita, KS.

The applicant requests a permit to conduct presence/absence surveys for the American burying beetle (*Nicrophorus americanus*), Hine's emerald dragonfly (*Somatochlora hineana*), Ozark hellbender (*Cryptobranchus allenganiensis bishopi*), Higgins eye pearlymussel (*Lampsilis higginsii*), winged mapleleaf mussel (*Quadrula fragosa*), Neosho mucket (*Lampsilis rafinesquenana*), pink mucket pearlymussel (*Lampsilis abrupta*), scaleshell mussel (*Leptodea leptodon*), sheepnose mussel (*Plethobasus cyphyus*), snuffbox mussel (*Epioblasma triquetra*), Curtis' pearlymussel (*Epioblasma florentina curtisii*), fat pocketbook (*Potamilus capax*), Topeka shiner (*Notropis Topeka*), spectaclecase mussel *(Cumberlandia monodonta,* pallid sturgeon (*Scaphirhynchus albus*), Quachita rock pocketbook (*Arkansia wheeleri*) in Kansas, Arkansas, Oklahoma, Nebraska, Missouri, and Iowa for the purpose of enhancing the species' survival.

Permit Application Number TE00670B

Applicant: South Dakota Game, Fish and Parks, Foss Building, 523 East Capitol, Pierre, SD.

The applicant requests a permit to conduct presence/absence surveys for the Topeka shiner (*Notropis topeka*) in South Dakota for the purpose of enhancing the species' survival.

National Environmental Policy Act

In compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), we have made an initial determination that the proposed activities in these permits are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement (516 DM 6 Appendix 1, 1.4C(1)).

Public Availability of Comments

All comments and materials we receive in response to these requests will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section of this notice.

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

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*).

Michael G. Thabault,

Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2014–29490 Filed 12–16–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNMA00000 L12200000.DF0000 15X L1010BP]

Notice of Public Meeting, Albuquerque District Resource Advisory Council Meeting, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act, the Bureau of Land Management (BLM) Albuquerque District Resource Advisory Council (RAC) will meet as indicated below.

DATES: The RAC will meet on Friday, January 16, 2015, at the Albuquerque District Office, 435 Montano Rd., Albuquerque, NM, 87107, from 9 a.m.–4 p.m.. The public may send written

comments to the RAC at the BLM Albuquerque District Office, 435 Montano Rd., Albuquerque, NM, 87107.

FOR FURTHER INFORMATION CONTACT: Martín Visarraga, BLM Albuquerque District Office, 435 Montano Rd., Albuquerque, NM 87107, 505–761–8902. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8229 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 10-member Albuquerque District RAC advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in New Mexico's Albuquerque District.

Planned agenda items include a welcoming and introduction of new Council members; election of chair and vice chair; an update on the Rio Puerco Management Plan, Sun Zia Southwest Transmission Project, Kinder Morgan Lobos CO_2 Pipeline Project, Mobile Workforce, Force Account Crew, law enforcement, Rio Puerco Management Committee, and a discussion on estray horses.

A half-hour comment period during which the public may address the RAC will begin at 11 a.m. All RAC meetings are open to the public. Depending on the number of individuals wishing to comment and time available, the time for individual oral comments may be limited.

Michael H. Tupper,

Deputy State Director, Lands and Resources.

[FR Doc. 2014–29523 Filed 12–16–14; 8:45 a.m.]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Number 1010–0048]

Information Collection: Geological and Geophysical Explorations of the Outer Continental Shelf; Submitted for OMB Review; Comment Request MMAA104000

ACTION: 30-day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Ocean Energy Management (BOEM) is notifying the public that we have submitted an information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval. The ICR concerns the paperwork requirements in the regulations under 30 CFR 551, Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf. This notice provides the public a second opportunity to comment on the paperwork burden of this collection.

DATES: Submit written comments by January 16, 2015.

ADDRESSES: Submit comments on this ICR to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_submission@omb.eop.gov* (email). Please provide a copy of your comments to the BOEM Information Collection Clearance Officer, Bureau of Ocean Energy Management, 381 Elden Street, HM–3127, Herndon, Virginia 20170 (mail) or *boemcmts@gmail.com* (email). Please reference ICR 1010–0048 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Office of Policy, Regulations, and Analysis at *boemcmts@gmail.com* (email) or (202) 513–7672. You may review the ICR and form online at *http://www.reginfo.gov*. Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1010–0048.

Title: 30 CFR 551, Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf.

Form: BOEM–0327, Requirements for G&G Explorations or Scientific Research on the Outer Continental Shelf.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of mineral resources on the OCS. The OCS Lands Act (43 U.S.C. 1340) states that ''any person authorized by the Secretary may conduct geological and geophysical explorations in the outer Continental Shelf, which do not interfere with or endanger actual operations under any lease maintained or granted pursuant to this subchapter, and which are not unduly harmful to aquatic life in such area.'' The section further requires that permits to conduct such activities may only be issued if it is determined that the applicant is qualified; the activities do not result in pollution or create hazardous or unsafe conditions; the activities do not unreasonably interfere with other uses of the area or disturb any site, structure, or object of historical or archaeological significance. Applicants for permits are required to submit form BOEM–0327 to provide the information necessary to evaluate their qualifications, and upon approval, respondents are issued a permit.

Also, as a Federal agency, we have a continuing affirmative duty to comply with the National Environmental Policy Act (NEPA), Endangered Species Act (ESA), and Marine Mammal Protection Act (MMPA). This includes a substantive duty not to take agency actions that are likely to jeopardize protected species as well as a procedural duty to consult with the Fish and Wildlife Service (FWS) and National Oceanic and Atmospheric Administration Fisheries (NOAA Fisheries) before engaging in a discretionary action that may affect a protected species.

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and the OMB Circular A–25 authorize Federal agencies to recover the full cost of services that confer special benefits. All G&G permits are subject to cost recovery, and BOEM regulations specify service fees for these requests.

Regulations to carry out these responsibilities are contained in 30 CFR 551 and are the subject of this information collection renewal. BOEM uses the information to ensure there is no environmental degradation, personal harm or unsafe operations and conditions, damage to historical or archaeological sites, or interference with other uses; to analyze and evaluate preliminary or planned drilling activities; to monitor progress and activities in the OCS; to acquire G&G data and information collected under a Federal permit offshore; and to determine eligibility for reimbursement from the government for certain costs. Information on the G&G characteristics of oil- and gas-bearing physiographic regions aids the Secretary in obtaining a proper balance among the potentials for environmental damage, the discovery of oil and gas, and associated impacts on affected coastal States.

In this renewal, we are including the estimated G&G permit applications and information that will be submitted for the Atlantic OCS. As a result of the BOEM Record of Decision regarding G&G survey activities on the Mid- and South Atlantic OCS Planning Areas (issued on July 23, 2014 (79 FR 42815)), BOEM will now consider G&G permit applications for this area.

Also in this renewal, BOEM is updating form BOEM–0327 to clarify

the types of copies being requested, delete incorrect language, make recommendations for faster processing, update addresses, and reference NEPA mitigation requirements. To respond to the types of questions BOEM receives from permittees on the form, BOEM is also clarifying wording, providing examples/tables to reduce confusion, and clarifying Regional differences, when necessary, to further assist permittees. BOEM is not asking for more information, just outlining current requirements in more detail.

These improvements do not change the hour burden for the form; however, based on public comments and respondent outreach, BOEM is making significant changes to the estimated hour burdens associated with the application. For the majority of permit applications, which are associated with G&G exploration in the Gulf of Mexico OCS Region, BOEM is increasing the hour burden from 3 to 300 hours. For applications in the frontier areas of the Alaska OCS Region and Atlantic OCS, BOEM is adjusting the burden to be significantly higher (from 300 to 1,000 hours), not because of the form changes, but because of the requirements to submit environmental information sufficient for the National Environmental Policy Act (NEPA) review about the effects of sound on marine mammals and other protected species. BOEM expects it will take more time for companies to compile and submit the necessary information to obtain the required authorizations to acquire a BOEM permit in these frontier areas, as well as to coordinate with other agencies. Due diligence, however, is still expected as full environmental review is authoritative within all OCS Regions.

BOEM believes the increased burden hours in this renewal accommodate the various requirements for all OCS Regions that companies must meet for environmental compliance to obtain G&G data, such as obtaining BOEM permits, coordinating their activities with the Department of Defense (DOD) and the National Aeronautics and Space Administration (NASA), as well as the additional requirement from the National Marine Fisheries Service (NMFS) to obtain an Incidental Take Authorization under the MMPA.

To complement the changes made in form BOEM–0327, BOEM is separating the requirements in the BOEM-issued permits by OCS Region to further assist permittees and clarify Regional differences. The actual permits are filled in by BOEM and do not incur a respondent hour burden.

We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under regulations at 30 CFR 551. No items of a sensitive nature are collected. Responses are mandatory.

Frequency: On occasion, annual, or as specified in permits.

Description of Respondents: Potential respondents comprise Federal OCS oil, gas, and sulphur permittees or notice filers.

Estimated Reporting and Recordkeeping Hour Burden: We estimate the burden for this collection to be about 40,954 hours. The following table details the individual components and respective hour burden estimates of this ICR.

BURDEN TABLE

Citation 30 CFR 551	Reporting and recordkeeping requirement	Non-hour cost burden *		
		Hour burden	Average number of annual responses	Annual burden hours
30 CFR 551.1 through 551.6				
551.4(a), (b); 551.5(a), (b), (d); 551.6; 551.7.	Apply for permits (form BOEM–0327) to conduct G&G exploration, including deep stratigraphic tests/revisions when necessary and mitigations. Submit required information in manner specified.	1,000 AK** .. 1,000 ATL** 300 GOM	4 Applications ..... 9 Applications ..... 74 Applications	4,000 9,000 22,200
		87 applications × $2,012 = $175,044		
551.4(b); 551.5(c), (d); 551.6.	File notices to conduct scientific research activities, including notice to BOEM prior to beginning and after concluding activities.	1	1 Notice	1
551.6(b); 551.7(b)(5)	Notify BOEM if specific actions should occur; report archaeological resources (no instances reported since 1982). Consult with other users.	1	1 Notice	1
Subtotal			89	35,202
			$175,044 non-hour cost burden	
30 CFR 551.7 through 551.9				
551.7; 551.8	Submit APD and Supplemental APD to BSEE	Burden included under BSEE regulations at 30 CFR 250, Subpart D (1014–0018)		0
551.7; 551.8(b)	Submit information on test drilling activities under a permit, including required information and plan revisions (e.g., drilling plan and environmental report).	1	1 Submission	1
551.7(c)	Enter into agreement for group participation in test drilling, including publishing summary statement; provide BOEM copy of notice/list of participants (no agreements submitted since 1989).	1	1 Agreement	1

BURDEN TABLE—Continued

Citation 30 CFR 551	Reporting and recordkeeping requirement	Non-hour cost burden *		
		Hour burden	Average number of annual responses	Annual burden hours
551.7(d)	Submit bond(s) on deep stratigraphic test and required securities.	Burden included under 30 CFR Part 556 (1010–0006)		0
551.8(a)	Request reimbursement for certain costs associated with BOEM inspections (no requests in many years).	1	1 Request	1
551.8(b), (c)	Submit modifications to, and status/final reports on, activities conducted under a permit.	38 AK**	4 Respondents × 10 Reports = 40.	1,520
		38 ATL**	9 Respondents × 10 Reports = 90.	3,420
		2 GOM	55 Respondents × 3 Reports = 165.	330
551.9(c)	Notify BOEM to relinquish a permit	½	2 Notices	1
Subtotal			300	5,274
30 CFR 551.10 through 551.13				
551.10(c)	File appeals	Exempt under 5 CFR 1320.4(a)(2), (c)		0
551.11; 551.12	Notify BOEM and submit G&G data and/or information collected and/or processed by permittees, bidders, or 3rd parties, etc., including reports, logs or charts, results, analyses, descriptions, information as required, and agreements, in manner specified.	4	40 Submissions	160
551.13	Request reimbursement for certain costs associated with reproducing data/information.	2	40 Submissions	80
Subtotal			80	240
30 CFR 551.14				
551.14(a), (b)	Submit comments on BOEM intent to disclose data and/or information to the public.	1	2 Comments	2
551.14(c)(2)	Submit comments on BOEM intent to disclose data and/or information to an independent contractor/agent.	1	2 Comments	2
551.14(c)(4)	Contractor/agent submits written commitment not to sell, trade, license, or disclose data and/or information without BOEM consent.	1	2 Commitments	2
551.1–551.14	General departure and alternative compliance requests not specifically covered elsewhere in part 551 regulations.	1	2 Requests	2
Subtotal			8	8
Extension for Permit Form & Recordkeeping				
551.14(b) (BOEM–0327)	Request extension of permit time period; enter agreements.	1	100 Extensions	100
	Retain G&G data/information for 10 years and make available to BOEM upon request.	1	130 Recordkeepers	130
Subtotal			230	230
Total Burden			707	40,954
			$175,044 non-hour cost burden.	

* Fees are subject to modification per inflation annually.
** Burden hours for the frontier areas of the Alaska Region and Atlantic OCS are significantly higher because of NEPA and mitigation requirements. BOEM is accounting for the total time to compile/submit the necessary information to obtain the required authorizations to acquire a BOEM permit. There are currently no such activities ongoing in the Pacific OCS Region.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified one non-hour cost burden for this collection of information. Under § 551.5(a) there is an application fee of $2,012 when respondents submit a permit application (refer to the table above).

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our burden estimates;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden on respondents.

To comply with the public consultation process, on August 22, 2014, BOEM published a **Federal Register** notice (79 FR 49807) announcing that we would submit this ICR to OMB for approval. This notice provided the required 60-day comment period. We received two sets of comments, which are discussed below.

Discussion of Public Comments Received

(1) International Assoc. of Geophysical Contractors (IAGC) With American Petroleum Institute (API)

The IAGC and API jointly submitted one set of comments. BOEM has addressed each point separately below.

Comment: Section D 3—Sound propagation information for Gulf of Mexico (GOM) Simsource Surveys is unwarranted.

Response: BOEM has given this comment due consideration and decided not to remove GOM simsource survey submissions at this time. Simsource surveys are new to the GOM and have not been considered previously in a Gulf of Mexico Programmatic Environmental Impact Statement. As such, in the near term, BOEM will scrutinize these surveys in more detail than surveys that use serial or sequential methods of energizing source arrays. After a suitable period of time, this review may not be needed.

Comment: Burden Estimates from BOEM are flawed. BOEM should recognize the substantial hour burden associated with permit application preparation. Expert consultants have detailed 300 to 1,000 hours for preparation of an application for G&G activity permits and marine mammal take permits.

Response: In response to the comment and to respondent feedback, BOEM is increasing the hour burden to fill out the permit application form for the Gulf of Mexico OCS Region from 3 to 300 hours and for the other OCS areas from 300 to 1,000 hours. Companies conducting G&G activities in the Gulf of Mexico OCS Region have experience in compiling and submitting the necessary information to obtain the required authorizations. However, in the frontier areas outside of the Gulf of Mexico OCS Region, BOEM expects it will take more time for companies to compile and submit the necessary information to obtain the required authorizations to acquire a BOEM permit in these areas as well as coordinate with other agencies. Therefore, the burden for applicants in the other OCS Regions to describe the environmental effects and proposed mitigations is estimated much higher.

Comment: Section D. Proprietary Information Attachment Required for an Application for Geophysical Permit—Item 10 is requiring the applicant to list ''all proposed initial and final processed data sets that will result from acquisition under this activity.'' An applicant can identify to BOEM what the original final processed data will be, but will be unable to provide other Forms of the processed data that the market may demand at the time the applicant submits form BOEM–0327.

Response: After review, BOEM will continue this requirement. The burden is considered minimal as BOEM only expects the permittee to conjecture what processing/end products are known at the time the permit application is submitted. This information often provides BOEM with a starting place for determining what type of products to expect from a survey. Inaccuracies or later changes are not penalized.

Comment: Section A. General Information—Item 4 requests an applicant provide a ''Commencement Date'' for the proposed geophysical activity. It is difficult for an applicant to provide a specific date because it is highly dependent on when the permit is used and when the vessel(s) and crew can be mobilized into the area of proposed activity.

Response: The ''expected'' commencement and ''expected'' completion date requirements will remain in the application as they provide BOEM with an idea of how long the permittee expects the duration of the activity to be. The planned time frame for the activity is especially critical in Alaska for NEPA review. These dates are critical for determining the possible environmental effects of the activity for such issues as the timing of subsistence hunting and presence of different protected species. The effective date of a permit will still be the issuance date that starts the 12-month clock ticking. For Atlantic OCS permits, BOEM plans to coordinate the effective date of the permit with the effective date of the Incidental Harassment Authorization to the extent practicable. The goal is to provide the permittee with as close to the maximum 12 months of operating time as possible.

Comment: Section A. General Information—Item 6 requests the applicant provide the vessel(s) name, registry number and registered owner(s). It can be difficult for an applicant to provide this information. This requirement does not accommodate the global nature of the geophysical industry nor the unpredictable timeline and regulatory uncertainty attendant with the requirements of the MMPA, NEPA and ESA. Geophysical contractors utilize vessels that are in high demand and that operate globally. It is difficult for an applicant to identify (with complete certainty) a specific vessel that will be available and will be used for a survey to be conducted several months to over a year later. Furthermore, the U.S. Coast Guard (USCG) is provided the same information at the time the vessel(s) mobilize into the U.S. OCS. Consequently, the information request in BOEM Form 0327 is unnecessary. In the alternative, the Associations recommend that BOEM Form 0327 require an applicant to submit the type of vessel(s) to be utilized in the survey (*e.g.,* vessel classification, streamer versus OBN, number of streamers) and at the time the geophysical contractor notifies the USCG, the BOEM will also be notified of vessel(s) name, registry number(s) and registered owner(s).

Response: Homeland Security, as well as the Department of Defense, has contacted BOEM in the past concerning survey vessels. Therefore, this requirement needs to be retained. However, BOEM agrees that the information for this requirement may or may not be known at the time the permit application is submitted. Currently, if the applicants know this information they can provide it with the application. If they do not, BOEM allows them to provide it at a later date *prior* to operations beginning. In these cases, email is often used to provide the information to BOEM in a timely manner. In a few instances, the permittee did not know which vessels were going to be used when the permit was issued. In these instances the permit cover letter stated that operations could not commence until the vessel information was provided to BOEM, usually by email for quick turnaround time. BOEM understands that this is of particular concern for Atlantic permits. The GOM flexibility will be extended to the Atlantic permits as well. The Alaska Region requires vessel information for the NEPA analysis. Companies are directed to provide vessel specs that represent the most likely type of vessels

that will be used for the activity. The final vessel information must be submitted ideally before the permit is issued, but definitely prior to commencement of operations pending approval from the NEPA staff.

(2) North American Submarine Cable Assoc. (NASCA)

Comment: NASCA urges BOEM to modify form BOEM–0327 to require permit applicants to identify and coordinate with submarine cables in the vicinity of any planned G&G activities.

Response: BOEM believes that ''other uses'' currently on the form would include submarine cable companies and that the current coordination processes with regard to submarine cables are working well in mature areas such as the Gulf of Mexico and should work just as well in the other Regions. In recognition of the concerns expressed in the NASCA comments, we have acknowledged such other uses by adding the words ''including submarine cables'' in form BOEM–0327 (under General Requirements paragraph E). Furthermore, we will add ''Submarine Cable Coordination'' to the list of Stipulations we attach to every permit. The NASCA would need to provide points of contact, etc., for the permittee. The matter would then be dealt with between the permittee and the submarine cable company.

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.

Dated: December 9, 2014.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulations, and Analysis.

[FR Doc. 2014–29564 Filed 12–16–14; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0072]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Employee Possessor Questionnaire

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit 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 proposed information collection is published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until February 17, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Christopher R. Reeves, Chief, Federal Explosives Licensing Center, 244 Needy Road, Martinsburg, WV 25405 or email at *Christopher.R.Reeves@usdoj.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection 1140–0072

1. *Type of Information Collection:* Extension without change of a currently approved collection.

2. *The Title of the Form/Collection:* Employee Possessor Questionnaire.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5400.28.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individual or households.

Other: Business or other for-profit.

Abstract: Each employee possessor in the explosives business or operations required to ship, transport, receive, or possess (actual or constructive), explosive materials must submit this form. The form will be submitted to ATF to determine whether the person who provided the information is qualified to be an employee possessor in an explosive business.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 10,000 respondents will take 20 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 3,334 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: December 11, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–29455 Filed 12–16–14; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0046]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Certification on Agency Letterhead Authorizing Purchase of Firearm for Official Duties of Law Enforcement Officer

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit 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 proposed information collection is published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until February 17, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Natisha Taylor, Firearms Industry Programs Branch, 99 New York Avenue NE., Washington, DC 20226 or email at *fipb-informationcollection@atf.gov* .

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection 1140–0046

1. *Type of Information Collection:* Extension without change of a currently approved collection.

2. *The Title of the Form/Collection:* Certification on Agency Letterhead Authorizing Purchase of Firearm for Official Duties of Law Enforcement Officer.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: State, Local, or Tribal Government.

Other: None.

Abstract: The letter is used by a law enforcement officer to purchase handguns to be used in his/her official duties from a licensed firearm dealer anywhere in the country. The letter shall state that the officer will use the firearm in official duties and that a records check reveals that the purchasing officer has no convictions for misdemeanor crimes of domestic violence.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50,000 respondents will take 8 minutes to complete and file the letter.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 6,667 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: December 11, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–29454 Filed 12–16–14; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF LABOR

Office of the Secretary of Labor

Intent To Issue Declaratory Order

AGENCY: Office of the Secretary of Labor, Department of Labor.

ACTION: Notice of intent to issue declaratory order; request for comment.

SUMMARY: The Secretary of Labor (Secretary) is considering issuing on his own motion a declaratory order confirming that he has exclusive authority to make legal and policy determinations based on his statutory and regulatory authority to administer and enforce the H–2B temporary labor certification program. Such a declaratory order would remove uncertainty about that authority created by a decision of the Board of Alien Labor Certification Appeals in *Island Holdings LLC,* 2013–PWD–00002 (BALCA Dec. 3, 2013) (en banc). The Secretary issues this Notice pursuant to the authority granted in the Administrative Procedure Act (APA), 5 U.S.C. 554(e), to issue declaratory orders ''to terminate a controversy or remove uncertainty.'' The Secretary will accept comments from the public on this Notice for 30 days, and may issue a declaratory order after consideration of all comments received in that timeframe.

DATES: This Notice is effective December 17, 2014. Interested persons are invited to submit written comments on this Declaratory Order on or before January 16, 2015.

ADDRESSES: You may submit comments, identified by docket number ETA–2014–0003, by any one of the following methods:

- *Federal e-Rulemaking Portal www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *Mail or Hand Delivery/Courier:* Please submit all written comments (including disk and CD–ROM submissions) to Adele Gagliardi, Administrator, Office of Policy Development and Research, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210.

Please submit your comments by only one method. Comments received by means other than those listed above or received after the comment period has closed will not be reviewed. The Departments will post all comments received on *http://www.regulations.gov* without making any change to the comments, including any personal information provided. The *http://www.regulations.gov* Web site is the Federal e-rulemaking portal and all comments posted there are available and accessible to the public. The Departments caution commenters not to include personal information such as Social Security Numbers, personal addresses, telephone numbers, and email addresses in their comments as such information will become viewable by the public on the *http://www.regulations.gov* Web site. It is the commenter's responsibility to safeguard his or her information. Comments submitted through *http://www.regulations.gov* will not include the commenter's email address unless the commenter chooses to include that information as part of his or her comment.

Postal delivery in Washington, DC, may be delayed due to security concerns. Therefore, the Departments encourage the public to submit comments through the *http://www.regulations.gov* Web site.

Docket: For access to the docket to read background documents or comments received, go to the Federal eRulemaking portal at *http://www.regulations.gov.* The Departments will also make all the comments either Department receives available for public inspection during normal business hours at the Employment and Training Administration (ETA) Office of Policy Development and Research at the above address. If you need assistance to review the comments, DOL will provide you with appropriate aids such as readers or print magnifiers. DOL will make copies of the rule available, upon request, in large print and as an electronic file on computer disk. DOL will consider providing the interim final rule in other formats upon request. To schedule an appointment to review the comments and/or obtain the rule in an alternate format, contact the ETA Office of Policy Development and Research at (202) 693–3700 (VOICE) (this is not a toll-free number) or 1–877–889–5627 (TTY/TDD).

FOR FURTHER INFORMATION CONTACT: For further information, contact William W. Thompson, Acting Administrator, Office of Foreign Labor Certification, ETA, U.S. Department of Labor, 200 Constitution Avenue NW., Room C–4312, Washington, DC 20210; Telephone (202) 693–3010 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

The Immigration and Nationality Act (INA) establishes the H–2B visa classification for a non-agricultural temporary worker ''having a residence in a foreign country which he has no intention of abandoning who is coming temporarily to the United States to perform . . . temporary [non-agricultural] service or labor if unemployed persons capable of performing such service or labor cannot be found in this country[.]'' 8 U.S.C. 1101(a)(15)(H)(ii)(b). The INA further requires an importing employer (H–2B employer) to petition the Department of Homeland Security (DHS) for classification of the prospective temporary worker as an H–2B nonimmigrant, and the petition must be made and approved before the beneficiary (H–2B worker) can be considered eligible for an H–2B visa or H–2B status. 8 U.S.C. 1184(c)(1). In adjudicating an H–2B petition, the INA requires DHS to consult with ''appropriate agencies of the Government[.]'' *Id.*

DHS has determined that in order to administer the INA's H–2B visa program it must consult with the Department of Labor (DOL) to determine whether U.S. workers capable of performing the temporary services or labor are available and that the foreign worker's employment will not adversely affect the wages or working conditions of similarly employed U.S. workers. 8 CFR 214.2(h)(6)(iii)(A). DHS's regulation requires employers to obtain certification from DOL that these conditions are met prior to submitting a petition to DHS. *Id.* DHS requires DOL to ''separately establish for the temporary labor program under his or her jurisdiction, by regulation at 20 CFR 655, procedures for administering that temporary labor program under his or her jurisdiction, and shall determine the prevailing wage applicable to an application for temporary labor certification.'' 8 CFR 214.2(h)(6)(iii)(D). DOL has rulemaking authority to carry out DHS's charge to establish rules governing the temporary labor certification process. *Louisiana Forestry Ass'n* v. *Secretary, U.S. Department of Labor,* 745 F.3d 653, 669, 672–675 (3rd Cir. 2014). DOL's H–2B regulations require a determination whether a qualified U.S. worker is available to fill the petitioning H–2B employer's job opportunity and whether a foreign worker's employment in the job opportunity will adversely affect the wages or working conditions of similarly employed U.S. workers. *See* 20 CFR part 655, subpart A. As part of DOL's labor certification process, DOL sets the wage that employers must offer and pay foreign workers entering the country on an H–2B visa. *See* 20 CFR 655.10.

On April 24, 2013, DHS and DOL (the Departments) issued an interim final rule (IFR) that revised DOL's method of determining the prevailing wage in the H–2B program.[1] Wage Methodology for the Temporary Non-Agricultural Employment H–2B Program, Part 2, 78 FR 24,047 (Apr. 24, 2013). The IFR was a direct response to a court order vacating a portion of the DOL's prevailing wage methodology and requiring the agency to come into compliance within 30 days. *Comite de Apoyo a los Trabajadores Agricolas (CATA)* v. *Solis,* 933 F. Supp. 2d 700 (E.D. Pa. 2013) (*CATA II*). The *CATA II* Court found that the 2008 regulation then being implemented to set the H–2B prevailing wage, which required the issuance of prevailing wages based on four artificial skill levels that were wholly irrelevant to unskilled H–2B work, violated the INA by allowing employers to pay substandard wages that harm the domestic labor market.[2] *CATA II,* 933 F. Supp. 2d at 713.[3] As a result, the IFR set a new,

[1] The Departments issued the 2013 IFR jointly to dispel questions that arose contemporaneously with its promulgation regarding the respective roles of the two agencies and the validity of DOL's regulations as an appropriate way to implement the interagency consultation specified in section 214(c)(1) of the INA, 8 U.S.C. 1184(c)(1). *See Bayou Lawn & Landscape Servs.* v. *Sec'y of Labor,* 713 F.3d 1080 (11th Cir. 2013) (concluding that plaintiffs are likely to prevail on their allegation that the Department of Labor lacks independent rulemaking authority under the INA to issue legislative regulations implementing its role in the H–2B program). However, the Eleventh Circuit in *Bayou* only reviewed the district court's entry of a preliminary injunction against implementation of DOL's H–2B rule issued before the joint IFR. Therefore, the Bayou decision only addressed the plaintiffs' likelihood of success on the merits, and was not a final judgment on the plaintiffs' claim that DOL is without authority to promulgate legislative rules in the H–2B program before the issuance of the joint IFR. The latter issue is currently before the district court awaiting decision on pending motions for summary judgment. As noted above and in sharp contrast to the *Bayou* case, in an APA challenge to the 2011 Wage Rule, which also tested DOL's authority to issue legislative rules in the H–2B program, the U.S. Court of Appeals for the Third Circuit held recently that ''DOL has authority to promulgate rules concerning the temporary labor certification process in the context of the H–2B program, and that the 2011 Wage Rule was validly promulgated pursuant to that authority.'' *La. Forestry Ass'n* v. *Perez,* 745 F.3d 653, 669 (3d Cir. Feb. 5, 2014); *see also G.H. Daniels & Assocs., Inc.* v. *Solis,* 2013 WL 5216453, *4–5 (D. Colo. Sept. 17, 2013) (DOL has authority to issue H–2B legislative rules), *appeal pending,* No. 13–1479 (10th Cir.).

[2] The *CATA II* order was the culmination of a years-long period of DOL rulemaking, challenges to that rulemaking, and Congressional riders that prevented the implementation of the agency's rules. In the preceding *CATA I* decision, Civ. No. 2:09–cv–240–LP, 2010 WL 3431761 (E.D. Pa. 2010), the district court concluded that the four-tiered skill levels in the 2008 prevailing wage rule were implemented without following the Administrative Procedure Act's notice-and-comment requirements. However, rather than vacate that methodology, the *CATA I* court left it in place and ordered DOL to issue a replacement rule that complied with the APA within 120 days. *CATA I,* slip op. at 27. DOL complied with the *CATA I* order by revising the H–2B wage regulation through notice and comment procedures (76 FR 3452, Jan. 19, 2011), but Congress, through appropriations riders, blocked its implementation. For a complete history of events leading up to the *CATA II* order and the IFR, see ''Notification of Status of the 2011 H–2B Wage Rule,'' 79 FR 14450 (March 14, 2014).

[3] As discussed further below in Sec. III, *supra,* the *CATA* orders anticipated that once DOL issued a valid regulatory method for determining the prevailing wage, the agency would also issue supplemental prevailing wage determinations to employers with current labor certifications to

legally valid prevailing wage standard to allow for an immediate adjustment of the wage rates for workers currently employed under the vacated 2008 wage rule. 78 FR at 24,056. In order to comply with the *CATA II* order, the preamble to the IFR notified the regulated community that the new prevailing wage rate under the IFR would apply to all employers currently employing H–2B workers in the U.S. upon individual notification to the employer of a new prevailing wage determination. *Id.* at 24,055.

To implement the IFR, on April 25, 2013, DOL issued an ''FAQ'' on its Web site informing the public that ''[e]mployers who have H–2B workers performing work that is based on the [vacated 2008 regulation] on or after April 24, 2013, will receive a new prevailing wage determination in accordance with the Wage Methodology IFR.'' Employment and Training Administration, Frequently Asked Questions, Interim Final Rule, Wage Methodology for the Temporary Non-Agricultural Employment H–2B Program, Part 2, at 1 (Apr. 25, 2013). DOL also advised the public, consistent with the statement in the preamble to the IFR, that ''employers are required to offer and pay [the new IFR] wage for any work performed on or after the date the employer receives the supplemental determination.'' *Id.* In addition, DOL indicated that employers were permitted under the regulation to file an appeal of any supplemental prevailing wage determination, but not based on a challenge to the occupational classification, because employers should have already raised that issue when they received their original prevailing wage determinations. *Id.* at 2. Immediately following the publication of the IFR, DOL issued supplemental prevailing wage determinations to all H–2B employers subject to the IFR, including employers currently employing H–2B workers under the vacated 2008 wage regime. In each supplemental prevailing wage determination, DOL informed the employer of its ability to seek a redetermination of the supplemental prevailing wage determination, pursuant to 20 CFR 655.10(g). On August 12, 2013, DOL completed the processing of new and supplemental prevailing wage determinations for all cases falling within the scope of the IFR.

II. The Island Holdings Challenge

Island Holdings, LLC, filed applications for labor certification with DOL in early 2013 for multiple H–2B nonimmigrant workers with proposed dates of employment into November 2013. When filing its applications for H–2B certification, Island Holdings agreed to pay the wage rate that equals or exceeds the highest of the most recent prevailing wage rate that is or will be issued by DOL for the time period the H 2B workers perform work in the United States. *See* ETA Form 9142—Appendix B.1. Before the publication of the IFR, DOL certified three Island Holdings' applications with prevailing wages based on the 2008 wage methodology, and these prevailing wages were valid generally through the end of 2013. Shortly after DOL published the IFR, the agency issued to Island Holdings three supplemental prevailing wage determinations (SPWDs) informing the company that it was required to pay new prevailing wage rates, as applicable under the IFR.

On May 23, 2013, Island Holdings filed an administrative appeal of DOL's supplemental prevailing wage determinations with the Board of Alien Labor Certification Appeals (BALCA), a group of Administrative Law Judges (ALJs) empowered to hear and decide appeals involving alien labor certification. 20 CFR 655.11(e); 655.33(e). The BALCA remanded the matter back to DOL to address Island Holdings' request for a redetermination under 20 CFR 655.10(g). Island Holdings subsequently sought a redetermination of DOL's supplemental prevailing wage determinations, but DOL determined that the agency's initial wage adjustments under the IFR were correct. Consistent with its statement in the IFR, DOL informed Island Holdings that the *CATA II* Court's vacatur order required the agency to replace the vacated 2008 prevailing wage rates with the valid prevailing wage rates under the IFR. DOL also informed Island Holdings that by signing ETA Form 9142, Appendix B.1, the company agreed, as a condition for importing foreign workers, that it would pay the prevailing wage rate in effect at the time the company employed H–2B workers in the United States. Because the 2008 wage rates had been vacated and were no longer in effect, DOL informed Island Holdings that the new IFR wage rates controlled.

Island Holdings again sought an administrative appeal of DOL's supplemental prevailing wage determinations under the IFR, which the BALCA docketed for en banc review. On December 3, 2013, the BALCA purportedly vacated DOL's supplemental prevailing wage determinations under the IFR. *See Island Holdings LLC,* 2013–PWD–00002 (BALCA Dec. 3, 2013) (en banc). Contrary to the Secretary of Labor's interpretation of the IFR stated in the preamble, the BALCA determined that DOL lacks the authority to issue supplemental prevailing wage determinations in cases where DOL has already approved labor certification applications based on the vacated 2008 prevailing wage rule. The BALCA rejected DOL's position, as stated in the preamble to the IFR, that the *CATA II* Court's vacatur order requires DOL to issue supplemental prevailing wage determinations to replace the vacated 2008 prevailing wage rates for all work performed by H–2B nonimmigrant workers after the issuance of the IFR. In addition, the BALCA determined that DOL lacks authority to require employers to pay the highest of the most recent prevailing wage that is or will be issued by DOL to the employer for the time period H–2B workers perform labor or services in the United States, despite the employer's signed agreement on ETA Form 9142, Appendix B.1, to pay the adjusted prevailing wage rate.

On December 11, 2013, CATA filed a civil action challenging the BALCA's *Island Holdings* decision as arbitrary, capricious, and in excess of law under the Administrative Procedure Act. *CATA* v. *Perez,*—FRD.—,2014 WL 3629528 (E.D. Pa. 2014) (CATA III). On January 10, 2014, CATA moved for summary judgment, seeking an order vacating the BALCA's decision. CATA argued that the BALCA, as subordinate Administrative Law Judges, lacks the authority to overrule the Secretary of Labor on issues of law and policy. Even if the BALCA had such authority, CATA contended that the BALCA's decision is an unreasonable and substantive alteration of the agency's legislative rule under the IFR, which violates the requirements of notice and comment rulemaking. In its pleadings, the Department of Labor agreed that *Island Holdings* does not represent the legal or policy decision of the Secretary of Labor as reflected in the IFR. The Department stated that the ''BALCA's Island Holdings decision represents a resolution of that individual case which is not subject to further administrative review . . ., but the BALCA's decision does not represent the legal position of the Secretary of Labor.'' On December 20, 2013, while the CATA III case was pending, DOL stayed further action on all pending supplemental prevailing wage determinations (approximately 1050 SPWDs), and has not yet taken any further action on them.

On July 23, 2014, the district court dismissed CATA's complaint, concluding that the plaintiffs were

correct the unlawful wage issued with those extant certifications.

without standing because there was no showing of agency action applying *Island Holdings* to CATA or its members. CATA III,—FRD.—,2014 WL 3629528, *7–8, The district court also held that the case did not involve final agency action because ''it is . . . the Secretary of Labor, and not the BALCA, that ultimately makes the policies and rules governing H–2B prevailing wages.'' *Id.* at 8. Finally, the court concluded that because the DOL was presently engaged in rulemaking to revise the H–2B wage methodology, adjudication would be premature because the agency may address the issue in that context. *Id.* at 8–10.

III. Basis for Declaratory Order

The BALCA's *Island Holdings* decision has created uncertainty about the Secretary of Labor's authority to set law and policy in the H–2B program generally, and about the immediate application of the revised wage regulation in the IFR to employers with H–2B workers employed at the time of the IFR but with prevailing wages set under the vacated 2008 wage rule. The decision has further cast uncertainty on the legal status of the pending supplemental prevailing wage determinations that DOL stayed shortly after the BALCA's decision. DOL's expectation was that the *CATA III* litigation, which squarely framed the issue whether the BALCA's *Island Holdings* decision exceeded the scope of its authority, would dispose of the matter in the Secretary's favor and resolve the uncertainty created by the BALCA. However, the district court chose to stay its hand, and returned resolution of the issue to DOL. Although the agency is currently preparing rulemaking to address issues involving the methodology to set the H–2B prevailing wage, that rulemaking cannot address the determination of rights and obligations under a prior rule, *Bowen* v. *Georgetown University Hosp.,* 488 U.S. 204, 208–211 (1988), and in any event will not be finalized until 2015 at the earliest.

The BALCA's *Island Holdings* decision does not reflect the legal position of the Secretary of Labor because the BALCA erroneously rejected the Secretary of Labor's own plain interpretation of the relevant regulatory provisions, as reflected in the preamble to the IFR and a separate notice amending ETA Form 9142, requiring H–2B employers to attest that they will pay at least the prevailing wage that ''is or will be issued by the Department'' during the course of the certified employment. *See* 78 FR at 24,055; 76 FR 21,036 (Apr. 14, 2011).[4] In dismissing the Secretary's preamble discussions, the BALCA ignored the established principle that a preamble statement to a rule constitutes the best evidence of the agency's contemporaneous interpretation of a regulation, to which the courts owe substantial deference. *See Public Citizen* v. *Carlin,* 184 F.3d 900, 911 (D.C. Cir. 1999); *cf. Dearborn Public Schools,* 1991–INA–222 (BALCA Dec. 7, 1993) (en banc), (BALCA, as a non-Article III court, lacks inherent authority to rule on the validity of a regulation).

Moreover, the BALCA's decision in *Island Holdings* that the Department is without authority to issue supplemental prevailing wage determinations is in direct opposition to the district court's orders in the *CATA* case, and potentially leaves the Department susceptible to conflicting legal obligations. *CATA I* ordered DOL to issue a new wage regulation that followed APA procedures. While DOL was drafting its new wage regulation to comply with *CATA I,* the district court concluded that it need not order DOL to issue conditional labor certifications to employers seeking to hire H–2B workers that would require employers to agree to pay a prevailing wage set by the new methodology as soon as that methodology became effective. Rather, the court specifically held that nothing in the existing H–2B regulations precluded DOL from issuing certifications conditioned on a promise to pay a new prevailing wage as soon as one became effective. *CATA I,* 2010 WL 4823236, at *2–3 (Nov. 24, 2010). The agency complied with the *CATA I* order in 2011 by issuing a new wage rule. 76 FR 3452. Congress then barred that 2011 wage rule from being implemented through a series of appropriations riders, causing the agency to continue applying the invalid 2008 wage rule. The court in *CATA II* then vacated the 2008 wage rule, concluding that prevailing wage determinations issued based upon the four-tiered wage rates in that rule resulted in adverse effect on U.S. workers' wages, and that the labor certifications based on such prevailing wages ''exceed the bounds of DOL's delegated authority.'' 933 F. Supp. 2d at 711–712. The court also found that the four-tiered wages required by the 2008 rule violated section 706(2)(A) of the APA, because it had consequences that ''plainly contradict congressional policy and render the 2008 Wage Rule invalid[.]'' *Id.* at 713. Once the court vacated the 2008 wage rule, it ceased to exist and DOL was obligated to move quickly to issue a valid replacement rule to fill the void. *Harper* v. *Virginia Dep't of Taxation,* 509 U.S. 86, 97 (1993); *Nat'l Fuel Gas Supply Corp.* v. *FERC,* 59 F.3d 1281, 1289 (D.C. Cir. 1995).

Taken together, these rulings make it clear that the *CATA* court expected that once DOL issued a valid regulatory method for determining the prevailing wage, the agency would also issue supplemental prevailing wage determinations to employers with current labor certifications to correct the unlawful wage issued with those extant certifications. The Secretary determined that the court's orders obliged the Department to issue the SPWDs, and that judgment is reflected in the IFR and its implementing guidance. The BALCA's *Island Holdings* decision directly controverts the *CATA* orders and, if abided, leaves the Department vulnerable to continuing legal challenges based on prevailing wage determinations invalidated by the IFR on April 24, 2013.

Even if DOL were not required under the *CATA* Court's decisions to adjust the prevailing wage obligations of H–2B employers under the IFR, the BALCA still erred in determining that DOL was not authorized to issue supplemental prevailing wage determinations. In 2011, DOL amended its ETA Form 9142, Appendix B.1, to require an agreement from all H–2B employers, as a condition for importing H–2B nonimmigrant workers, to pay the prevailing wage rate in effect for the pay period of work encompassed by the employer's labor certification application for H–2B nonimmigrant workers. 76 FR at 21,036–39. In the preamble to the **Federal Register** notice announcing the amendment to ETA Form 9142, Appendix B.1, the Assistant Secretary of Labor stated that DOL requires all employers who apply for an H–2B labor certification to agree, as a condition of receiving the H–2B labor certification, to pay the prevailing wage rate in effect for the period of work encompassed by the employers' labor certification applications. *Id.* at 21,036. When publishing the IFR, the Secretary of Labor again stated that all employers are required to comply with this condition after receiving a supplemental

[4] When it published the new ETA Form 9142 requiring employers seeking a labor certification to swear under penalty of perjury that they would pay at least the prevailing wage that ''is or will be issued by the Department'' during the course of the certified employment, the Department explained that when a new wage rate became effective as a result of a revision to the methodology to determine the prevailing wage, employers would be required to pay the prevailing wage rate in effect for the period of work encompassed by their application, which could result in two wage rates being applicable to a single application. 76 FR 21,036. Employers have been voluntarily signing this attestation for over three years.

prevailing wage determination under the IFR. 78 FR at 24,055. Thus, DOL's issuance of supplemental prevailing wage determinations under the IFR is authorized by the contractual conditions to which the employers agreed when signing ETA Form 9142, Appendix B.1, and the Secretary's interpretation of the scope of the IFR wage obligations for employers currently employing H–2B workers under wage rates that have been vacated or rendered legally erroneous.

In the case under review, Island Holdings willingly agreed to the wage adjustment conditions when the company signed ETA Form 9142, Appendix B.1. Island Holdings agreed to pay the wage rate that equals or exceeds the highest of the most recent prevailing wage rate that is or will be issued by DOL for the time period the H–2B workers perform work in the United States. Because Island Holdings specifically agreed to contractual terms set by DOL as a condition for importing foreign workers, the company remains bound to those contractual terms. *Woodside Village* v. *Secretary of Labor,* 611 F.2d 312, 315 (9th Cir. 1980); *Vulcan Arbor Hill Corp.* v. *Reich,* 81 F.3d 1110, 1115–16 (D.C. Cir. 1996). Island Holdings, and all similarly situated H–2B employers, remain bound by the voluntary and unconditional promise to pay the wage rate that equals or exceeds the highest of the most recent prevailing wage rate that is or will be issued by DOL for the time period the H–2B workers perform work in the United States, including the new IFR wage rates. *Frederick County Fruit Growers* v. *Martin,* 968 F.2d 1265, 1269 (D.C. Cir. 1992). The Secretary's position on this issue was clearly stated in the preamble to the IFR, which indicated that employers are required to pay the higher IFR wage rates based on the employers' signed agreements under Appendix B.1 to ETA Form 9142. 78 FR at 24055. Therefore, the BALCA's determination that employers are not required to pay the adjusted wage rates under the supplemental prevailing wage determinations was a legal error issued contrary to the Secretary's clear direction on this precise issue under the IFR.

Accordingly, pursuant to the authority granted to DOL under 5 U.S.C. 554(e), the Secretary is now considering issuing on his own motion a declaratory order to clarify his authority to set law and policy in the H–2B labor certification program, and to resolve the controversy arising from the BALCA's legally erroneous decision. The BALCA's *Island Holdings* decision does not represent the legal or policy position of the Secretary of Labor. The Administrative Law Judges composing the BALCA are subordinate employees of the agency. *See* 5 U.S.C. 3105; 52 FR at 11,217; Dep't of Justice, Legal Counsel Opinion, 14 Op. O.L.C. 1, 2–3 (1990). It is a basic principle of administrative law that the agency makes law and policy, not subordinate ALJs. *See Ho* v. *Donovan,* 569 F.3d 677, 682 (7th Cir. 2009); *Croplife* v. *EPA,* 329 F.3d 876, 882 (D.C. Cir. 2003); *Iran Air* v. *Kugelman,* 996 F.2d 1253, 1260 (D.C. Cir. 1993); *Nash* v. *Bowen,* 869 F.2d 675, 680 (2d Cir. 1989); Admin. Conf. of the United States, Recommendation 92–7, 57 FR 61,759, 61,763 (Dec. 29, 1992). The BALCA ALJs' authority is limited to non-lawmaking functions, including determining issues of fact and applying undisputed law to the facts of an employer's particular case.

Apart from the general principle of administrative law that the BALCA ALJs do not have authority to speak for the agency on questions of law and policy, under DOL's regulation the BALCA does not have delegated authority to speak for the agency. Unlike the Secretary's express delegation of his authority to the Administrative Review Board (ARB), *see* 77 FR 69378 (Secretary's Order 1–2012), the agency has never endowed the BALCA with authority to speak for the Secretary on legal issues, *see* 52 FR at 11,217–18. Courts have recognized that the ARB speaks for the agency because it has delegated authority, *see Sasse* v. *DOL,* 409 F.3d 773, 778–79 (6th Cir. 2005), but the BALCA lacks such delegation. Although the agency's administrative appellate regime may terminate with the BALCA's review because there is no procedure for appealing to a higher agency official, that termination does not create delegated authority in the BALCA to make law or policy for the agency. The lack of further administrative review simply means that the BALCA's decision is the final agency action for purposes of judicial review. *See* 5 U.S.C. 704; *cf.* Tom C. Clark, *Attorney General's Manual on the Administrative Procedure Act* 83 (1947). However, as a neutral fact finder and arbiter of an employer's complaint, the BALCA's decisions do not necessarily represent the agency's authoritative interpretation of the regulation. *Cf. Martin* v. *Occupational Safety and Health Review Comm'n,* 499 U.S. 144, 154–55 (1991).[5]

The Secretary establishes H–2B wage policy and any related, governing legal standards. If the Secretary determines that the BALCA's decision rests on a legal error or departs from the Secretary's announced legal interpretation or policy, the Secretary may issue in his discretion a declaratory order overruling the BALCA. 5 U.S.C. 554(e).

The Secretary proposes issuing a declaratory order to overrule the BALCA's decision and legal conclusions in *Island Holdings,* and to reaffirm the Secretary's interpretation of the regulations, as stated in the preamble to the IFR. The Secretary does not intend through the proposed declaratory order to create a new rule, but seeks to resolve and clarify the agency's prior interpretation of the H–2B regulation and apply this interpretation, as originally intended, to the undisputed facts in *Island Holdings.* Thus, the proposed declaratory order is limited to the concrete and narrow question of law about the scope of the IFR as applied to the factual scenario in *Island Holdings,* which order will eliminate confusion and uncertainty created by the *Island Holdings* decision related to the Secretary's authority to set law and policy in the H–2B program, and the related status of the supplemental prevailing determinations issued to the employer in *Island Holdings* under the IFR. In addition, a final declaratory order on this issue will also establish binding precedent for resolution of all supplemental prevailing wage determinations under the IFR involving similarly situated parties. Following the issuance of such an order, the supplemental prevailing wage determinations at issue in *Island Holdings* and any similar pending cases will be handled and finally resolved in accordance with the final declaratory order.

Since the proposed declaratory order involves solely questions of law and the application of law to undisputed facts relating to the issuance of the supplemental prevailing wage determinations in *Island Holdings,* the Secretary seeks comment from the public in the nature of legal briefing related to the proposed legal

[5] Even under a split enforcement regime where Congress delegates to a neutral adjudicatory board the authority to hear claims or sanctions brought by the agency with enforcement authority, the Supreme Court has held that the enforcement agency with authority to administer the statute has jurisdiction to issue binding interpretations of the agency's regulation. *See Martin* v. *OSHRC,* 499 U.S. 144, 154–55 (1991). A neutral adjudicatory board outside the agency does not have authority to issue binding interpretations of law because the purpose of the adjudicatory board is to determine whether the agency's action is consistent with the regulation, which the agency defines in the first instance. *Id. Martin*'s principle that the enforcement agency has policy making authority has even more force in this case, where DOL does not operate under a split enforcement regime in H–2B context and a single agency has retained to itself all enforcement functions.

determinations stated in this notice. In order to establish the record for this adjudicatory proceeding, the Department will provide access to the following documents on the *http://www.regulations.gov* Web site under the docket number ETA–2014–0003: (1) The Department's April 24, 2013 Interim Final Rule; (2) the *CATA I* and *CATA II* decisions; and (3) the *Island Holdings* decision.

Signed: at Washington, DC, this 2nd of December 2014.

Thomas E. Perez,

Secretary of Labor.

[FR Doc. 2014–28823 Filed 12–16–14; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–85,058]

Learjet Inc., a Kansas Corporation, a Wholly Owned Indirect Subsidiary of Bombardier, Inc., Including On-Site Leased Workers From Additional Technical Support, Inc., Aero Structures Analysis Partners, LLC, Aerotek Aviation, Black Diamond Networks, Bruce Lutz Consultant, Choson Resource, CJ Johnson Enterprises, Inc. Daca International, Dark Space, Inc., Donatech Corporation, Experts Technical Staffing, Foster Design Co., Inc., Global Contract Professionals, Inc., Hi-Tek Professionals, Inconen, Johnson Service Group, Jonas Services, Inc., Noramtec, Owens Aerospace Of America, Inc., PDS Engineering, PDS Production, PCO Innovation, Precision Personnel, Precision Resources Co., Inc., Spencer Reed Group, Strom, Valper Engineering, Volt Technical Resources, LLC and Advanced Technology Innovation Corporation, Wichita, Kansas; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on May 6, 2014, applicable to workers of Learjet Inc., a Kansas Corporation, a wholly owned indirect subsidiary of Bombardier, Inc., including on-site leased workers from Additional Technical Support, Inc., Aero Structures Analysis Partners, LLC, Aerotek Aviation, Black Diamond Networks, Bruce Lutz Consultant, Choson Resource, CJ Johnson Enterprises, Inc. Daca International, Dark Space, Inc., Donatech Corporation, Experts Technical Staffing, Foster Design Co., Inc., Global Contract Professionals, Inc., Hi-Tek Professionals, Inconen, Johnson Service Group, Jonas Services, Inc., Noramtec, Owens Aerospace Of America, Inc., PDS Engineering, PDS Production, PCO Innovation, Precision Personnel, Precision Resources Co., Inc., Spencer Reed Group, Strom, Valper Engineering, and Volt Technical Resources, LLC, Wichita, Kansas.

At the request of company official, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of aircraft.

The company reports that workers leased from Advanced Technology Innovation Corporation were employed on-site at Learjet Inc., Wichita, Kansas. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Advanced Technology Innovation Corporation, working on-site at the Wichita, Kansas location of Learjet Inc., a Kansas Corporation, a wholly owned indirect subsidiary of Bombardier, Inc.

The amended notice applicable to TA–W–85,058 is hereby issued as follows:

''All workers of Learjet Inc., a Kansas Corporation, a wholly-owned subsidiary of Bombardier, Inc., including on-site leased workers from Additional Technical Support, Inc., Aero Structures Analysis Partners, LLC, Aerotek Aviation, Black Diamond Networks, Bruce Lutz Consultant, Choson Resource, CJ Johnson Enterprises, Inc. Daca International, Dark Space, Inc., Donatech Corporation, Experts Technical Staffing, Foster Design Co., Inc., Global Contract Professionals, Inc., Hi-Tek Professionals, Inconen, Johnson Service Group, Jonas Services, Inc., Noramtec, Owens Aerospace Of America, Inc., PDS Engineering, PDS Production, PCO Innovation, Precision Personnel, Precision Resources Co., Inc., Spencer Reed Group, Strom, Valper Engineering, Volt Technical Resources, LLC, and Advanced Technology Innovation Corporation, Wichita, Kansas, who became totally or partially separated from employment on or after February 6, 2013 through May 6, 2016, and all workers in the group threatened with total or partial separation from employment on the date of certification through May 6, 2016, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC this 4th day of December, 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–29510 Filed 12–16–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–82,920]

Cooper Interconnect, LLC, A Subsidiary of Eaton Corporation, Including On-Site Leased Workers From Aerotek, Adecco, J&J Staffing, Superior Talent and Randstad, Salem, New Jersey; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on July 30, 2013, applicable to workers of GDF SUEZ Mt. Tom Power Plant, a subsidiary of Cooper Interconnect, LLC, a subsidiary of Eaton Corporation, including on-site leased workers from Aerotek, Addeco, J&J Staffing and Superior Talent Resources, Salem, New Jersey. The Department's notice of determination was published in the **Federal Register** on August 27, 2013 (78 FR 52978).

In response to a request by the state workforce office in Trenton, New Jersey, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of electrical connectors.

The investigation confirmed that leased workers from Randstad worked on-site at the subject firm.

Based on these findings, the Department is amending this certification to include on-site leased workers from Randstad, Salem, New Jersey.

The amended notice applicable to TA–W–82,920 is hereby issued as follows:

''All workers of Cooper Interconnect, LLC, a subsidiary of Eaton Corporation, including on-site leased workers from Aerotek, Adecco, J&J Staffing, Superior Talent Resources and Randstad, Salem, New, who became totally or partially separated from employment on or after July 18, 2013, through July 30, 2015, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under

Chapter 2 of Title II of the Trade Act of 1974, as amended.''

Signed in Washington, DC this 2nd day of December, 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–29509 Filed 12–16–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 29, 2014.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 29, 2014.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 4th day of December 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[14 TAA petitions instituted between 11/24/14 and 11/28/14]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
85665	Mondi Group (Workers)	New Philadelphia, OH	11/24/14	11/13/14
85666	Philips Lightolier (State/One-Stop)	Fall River, MA	11/24/14	11/21/14
85667	JDS Uniphase (Company)	Milpitas, CA	11/25/14	11/24/14
85668	Pamco Machine Company (State/One-Stop)	Lewiston, ME	11/25/14	11/24/14
85669	Smith Detection, Inc (Company)	Edgewood, MD	11/25/14	11/24/14
85670	Verizon Communications (Union)	Erie, PA	11/25/14	11/24/14
85671	DIEHL Controls North America, Inc. (Company)	Naperville, IL	11/25/14	11/06/14
85672	Twin Rivers Paper LLC (Union)	Madawaska, ME	11/26/14	11/26/14
85673	Quantum Foods (Workers)	Bolingbrook, IL	11/26/14	11/25/14
85674	Levi Strauss and Co (State/One-Stop)	Eugene, OR	11/26/14	11/25/14
85675	Hewlett Packard Co. (State/One-Stop)	Corvallis, OR	11/26/14	11/25/14
85676	Syncreon (Company)	Trotwood, OH	11/28/14	11/26/14
85677	Hitachi Zosen Catalyst USA, LLC (Company)	Scottsboro, AL	11/28/14	11/26/14
85678	Navister (Workers)	Garland, TX	11/28/14	11/25/14

[FR Doc. 2014–29507 Filed 12–16–14; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *November 24, 2014 through November 28, 2014.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. the sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. there has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. the country to which the workers' firm has shifted production of the articles to a beneficiary country under

the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. there has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (*i.e.,* conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

85,578, Avery Dennison, Lenoir, North Carolina. December 6, 2014.

85,578A, Leased Workers of Manpower and Zero Chaos, Lenoir, North Carolina. October 7, 2013.

85,587, OMCO Maching Concepts, Inc., Winchester, Indiana. October 9, 2013.

85,599, Donna Morgan LLC, New York, New York. October 15, 2013.

85,608, Silberline Manufacturing Company, Inc., Tamaqua, Pennsylvania. October 20, 2013.

85,608A, Silberline Manufacturing Company, Inc., Tamaqua, Pennsylvania. October 20, 2013.

85,608B, Silberline Manufacturing Company, Inc., Lansford, Pennsylvania. October 20, 2013.

85,608C, Silberline Manufacturing Company, Inc., Decatur, Indiana. October 20, 2013.

85,614, Metglas, Inc., Conway, South Carolina. October 22, 2013.

85,626, Air System Components, Inc., El Paso, Texas. July 12, 2014.

85,626A, A&A H.G. Arias & Associates, El Paso, Texas. October 31, 2013.

85,628, Devro, Inc., Swansea, South Carolina. November 4, 2013.

85,635, United Technologies Aerospace Systems (UTAS), Windsor Locks, Connecticut. November 17, 2014.

85,636, Flextronics, Austin, Texas. November 9, 2013.

85,651, First Circuit, Inc., Vista, California. November 17, 2013.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

85,645, Cardinal Health, McDonough, Georgia.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

85,516, Bimbo Bakeries USA, Inc., Fresno, California.

85,534, Pendleton Grain Growers Inc., Hermiston, Oregon.

85,534A, Pendleton Grain Growers Inc., Hermiston, Oregon.

85,534B, Pendleton Grain Growers Inc., Hermiston, Oregon.

85,534C, Pendleton Grain Growers Inc., Pendleton, Oregon.

85,534D, Pendleton Grain Growers Inc., Pendleton, Oregon.

85,534E, Pendleton Grain Growers Inc., Pendleton, Oregon.

85,534F, Pendleton Grain Growers Inc., Pendleton, Oregon.

85,534G, Pendleton Grain Growers Inc., Freewater, Oregon.

85,534H, Pendleton Grain Growers Inc., Island City, Oregon.

85,617, Day & Zimmermann, Inc., Parsons, Kansas.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

85,640, Covidien LP, Mansfield, Massachusetts.

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

85,644, Nokia Siemens Networks US, LLC, Arlington Heights, Illinois.

85,653, Mahar Tool Supply, Inc., Longview, Texas.

85,654, AeroTek, Longview, Texas.
85,655, Human Technologies, Longview, Texas.

I hereby certify that the aforementioned determinations were issued during the period of *November 24, 2014 through November 28, 2014.* These determinations are available on the Department's Web site *www.tradeact/taa/taa_search_form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC, this 9th day of December 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–29508 Filed 12–16–14; 8:45 am]

BILLING CODE 4510–FN–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 14–09]

Report on the Selection of Eligible Countries for Fiscal Year 2015

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: This report is provided in accordance with section 608(d)(1) of the Millennium Challenge Act of 2003, Public Law 108–199, Division D, (the ''Act''), 22 U.S.C. 7708(d)(1).

Dated: December 12, 2014.

Thomas G. Hohenthaner,

Vice President/General Counsel and Corporate Secretary (Acting), Millennium Challenge Corporation.

Report on the Selection of Eligible Countries for Fiscal Year 2015

Summary

This report is provided in accordance with section 608(d)(1) of the Millennium Challenge Act of 2003, as amended, Public Law 108–199, Division D, (the ''Act'') (22 U.S.C. 7707(d)(1)).

The Act authorizes the provision of Millennium Challenge Account (''MCA'') assistance under section 605 of the Act (22 U.S.C. 7704) to countries that enter into compacts with the United States to support policies and programs that advance the progress of such countries in achieving lasting economic growth and poverty reduction, and are in furtherance of the Act. The Act requires the Millennium Challenge Corporation (''MCC'') to determine the countries that will be eligible to receive MCA assistance for the fiscal year, based on their demonstrated commitment to just and democratic governance, economic freedom, and investing in their people, as well as on the opportunity to reduce poverty and generate economic growth in the country. The Act also requires the submission of reports to appropriate congressional committees and the publication of notices in the Federal Register that identify, among other things:

1. The countries that are ''candidate countries'' for MCA assistance for fiscal year (''FY'') 2015 based on their per-capita income levels and their eligibility to receive assistance under U.S. law, and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act (22 U.S.C. 7707(a)));

2. The criteria and methodology that the Board of Directors of MCC (the ''Board'') will use to measure and evaluate the policy performance of the ''candidate countries'' consistent with the requirements of section 607 of the Act in order to select ''MCA eligible countries'' from among the ''candidate countries'' (section 608(b) of the Act (22 U.S.C. 7707(b))); and

3. The list of countries determined by the Board to be ''MCA eligible countries'' for FY 2015, with justification for eligibility determination and selection for compact negotiation, including with which of the MCA eligible countries the Board will seek to enter into MCA compacts (section 608(d) of the Act (22 U.S.C. 7707(d))).

This is the third of the above-described reports by MCC for FY 2015. It identifies countries determined by the Board to be eligible under section 607 of the Act (22 U.S.C. 7706) for FY 2015 and countries with which the MCC will seek to enter into compacts under section 609 of the Act (22 U.S.C. 7708), as well as the justification for such decisions. The report also identifies countries determined by the Board to be eligible for MCC's Threshold Program under section 616 of the Act (22 U.S.C. 7715).

Eligible Countries

The Board met on December 10, 2014, to select countries that will be eligible for MCA compact assistance under section 607 of the Act (22 U.S.C. 7706) for FY 2015. The Board selected the following countries as eligible for such assistance for FY 2015: Mongolia, Nepal, and the Philippines. The Board also reselected the following countries as eligible for FY 2015 MCA compact assistance—Benin, Lesotho, Liberia, Morocco, Niger, and Tanzania. Sierra Leone, which was not reselected for compact assistance, was selected as eligible for threshold assistance. Cote d'Ivoire was also selected as eligible for threshold assistance, and Guatemala was reselected for eligibility for threshold program funds from FY 2015. The Board also confirmed its support for MCC's efforts to explore new partnerships in South Asia that could contribute to regional economic benefits. This is because, under the right circumstances, such a regional approach may present opportunities to take advantage of higher rates of return on investment and/or larger-scale reductions in poverty.

Criteria

In accordance with the Act and with the ''Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance in Fiscal Year 2015'' formally submitted to Congress on September 18, 2014, selection was based primarily on a country's overall performance in three broad policy categories: Ruling Justly, Encouraging Economic Freedom, and Investing in People. The Board relied, to the maximum extent possible, upon transparent and independent indicators to assess countries' policy performance and demonstrated commitment in these three broad policy areas. The Board compared countries' performance on the indicators relative to their income-level peers, evaluating them in comparison to either the group of low income scorecard countries (''LIC'') or the group of lower middle income scorecard countries (''LMIC'').

The criteria and methodology used to assess countries on the annual scorecards are outlined in the ''Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance in Fiscal Year 2015'' (*www.mcc.gov/pages/docs/doc/report-selection-criteria-and-methodology-fy15*). Scorecards reflecting each country's performance on the indicators are available on MCC's Web site at *www.mcc.gov/scorecards.*

The Board also considered whether any adjustments should be made for data gaps, data lags, or recent events since the indicators were published, as well as strengths or weaknesses in particular indicators. Where appropriate, the Board took into account additional quantitative and qualitative information, such as evidence of a country's commitment to fighting corruption, investments in human development outcomes, or poverty rates. For example, for additional information in the area of corruption, the Board considered how a country is evaluated by supplemental sources like

Transparency International's Corruption Perceptions Index, the Global Integrity Report, Open Government Partnership status, and the Extractive Industry Transparency Initiative, among others, as well as on the defined indicator. The Board may also take into account the margin of error around an indicator, when applicable. In keeping with legislative directives, the Board also considered the opportunity to reduce poverty and promote economic growth in a country, in light of the overall information available, as well as the availability of appropriated funds.

This was the sixth year the Board considered the eligibility of countries for subsequent compacts, as permitted under section 609(k) of the Act (22 U.S.C. 7708(k)). The Board also considered the eligibility of countries for initial compacts. The Board sees the selection decision as an annual opportunity to determine where MCC funds can be most effectively invested to support poverty reduction through economic growth in relatively well-governed, poor countries. The Board carefully considers the appropriate nature of each country partnership—on a case by case basis—based on factors related to economic growth and poverty reduction, the sustainability of MCC's investments, and the country's ability to attract and leverage public and private resources in support of development.

MCC's engagement with partner countries is not open-ended, and the Board is very deliberate when determining eligibility for follow-on partnerships. In determining subsequent compact eligibility, the Board considered—in addition to the criteria outlined above—the country's performance implementing its first compact, including the nature of the country's partnership with MCC, the degree to which the country has demonstrated a commitment and capacity to achieve program results, and the degree to which the country has implemented the compact in accordance with MCC's core policies and standards. To the greatest extent possible, this was assessed using pre-existing monitoring and evaluation targets and regular quarterly reporting.

This information was supplemented with direct surveys and consultation with MCC staff responsible for compact implementation, monitoring, and evaluation. MCC published a Guide to the Supplemental Information Sheet (*www.mcc.gov/pages/docs/doc/pub-guide-to-supplemental-information-fy15*) and a Guide to the Compact Survey Summary (*www.mcc.gov/pages/docs/doc/summary-compact-survey-summary-fy15*) in order to increase transparency about the type of supplemental information the Board uses to assess a country's policy performance and compact implementation performance. The Board also considered a country's commitment to further sector reform, as well as evidence of improved scorecard policy performance.

As with previous years, a number of countries that performed well on the quantitative elements of the selection criteria (*i.e.,* on the policy indicators) were not chosen as eligible countries for FY 2015. FY 2015 was a particularly competitive year: seven countries were already working to develop compacts, multiple countries passed the scorecard (some for the first time), and funding was limited due to budget constraints. As a result, only three countries that passed the scorecard were newly selected for MCC compact eligibility, and two for the threshold program (one of which was Sierra Leone, moving from compact to threshold program eligibility).

Countries newly selected for compact eligibility

Using the criteria described above, Mongolia, Nepal, and the Philippines are the only candidate countries under section 606(a) of the Act (22 U.S.C. 7705(a)) that were newly selected as eligible for MCA assistance for a compact under section 607 of the Act (22 U.S.C. 7706).

Mongolia: After graduating to LMIC status in FY 2013, Mongolia has passed MCC's scorecard criteria for two consecutive years and has shown improvement on the Control of Corruption indicator. It also remains a strong democracy in its region. Rapid growth in the mining sector has fostered recent economic growth; however, 27 percent of the population live below the national poverty line, on par with countries such as Honduras or Nicaragua. The country successfully implemented its first compact, which focused on strengthening property rights, reducing non-communicable diseases, bolstering vocational education, reducing air pollution, and constructing an all-weather road to link markets.

Nepal: Nepal has consistently passed the scorecard criteria for four consecutive years. Over the past year, Nepal held successful elections and made progress towards completing a draft constitution, thus demonstrating continued progress toward institutionalizing democratic governance. Nepal has also shown stronger policy performance as the political situation has stabilized, including improved performance on the Political Rights indicator. Selection for a compact offers Nepal a significant opportunity for poverty reduction in a critically important region. A compact investment will build on the economic analysis and development work completed during eligibility for the Threshold Program.

Philippines: The Philippines once again met MCC's scorecard criteria in FY 2015, despite graduating to LMIC status in FY 2012, where the standards are higher and therefore more difficult to meet. The Philippines' improvement has been most notable on the Control of Corruption indicator, on which it improved from the 24th to 61st percentile in just three years. The country is on track to successfully complete its current compact, which focuses on reducing transportation costs through road rehabilitation, as well as bringing efficiencies to tax collection and investing in small-scale, community-driven development projects.

Countries reselected to continue compact development

Five of the countries selected as eligible for MCA compact assistance for FY 2015 were previously selected as eligible in FY 2014. These countries include Lesotho, Liberia, Morocco, Niger, and Tanzania. The Board reselected these countries based on their continued or improved policy performance since their prior selection.

In FY15, unlike in FY14, Benin also meets the scorecard criteria, including passing the Control of Corruption hurdle. The Board reselected Benin as compact eligible, as well.

Countries selected as eligible to receive threshold assistance

The Board selected Cote d'Ivoire as eligible to receive threshold assistance. After years of working with MCC and MCC indicator institutions in order to strengthen their scorecard performance, Cote D'Ivoire went from passing 5 to 10 indicators over the last two years, due to updating data and pursuing policy reforms linked to the scorecard. In FY 2015, Cote D'Ivoire meets the minimum scorecard criteria for the first time, passing 10 indicators, including both hard hurdles. Selection for eligibility for threshold assistance will allow Cote d'Ivoire an opportunity to further strengthen its scorecard performance, and allow MCC the opportunity to work with the government on the country's ongoing efforts in policy reform.

The Board also selected Sierra Leone as eligible to receive threshold assistance. Sierra Leone has been

committed to reform and is a strong partner of MCC—taking numerous steps to improve transparency and fight corruption over 2014, even in the face of the Ebola crisis. Sierra Leone also continued to improve its overall scorecard performance by meeting 12 of 20 indicators this year versus 11 of 20 last year. However, Sierra Leone did not meet MCC's scorecard criteria for the second year, again narrowly missing a passing score on the Control of Corruption indicator. By selecting Sierra Leone as eligible for threshold assistance, MCC aims to support the government in its efforts to continue its positive overall policy trajectory, while also allowing MCC to bolster Sierra Leone's efforts by supporting continued institutional and policy reforms as the country emerges from its Ebola crisis.

Countries reselected to continue developing threshold programs

This year the Board reselected Guatemala as eligible to continue developing a threshold program. Guatemala continues to pass more than half of the scorecard overall by meeting 11 of 20 indicators. It also continues to meet the Democratic Rights hurdle. Guatemala improved on the Control of Corruption indicator and currently performs on the median in the 50th percentile.

Ongoing review of partner countries' policy performance

Countries already implementing compacts do not need to be reselected each year in order to continue implementation. Once MCC makes a commitment to a country through a compact, MCC does not consider the country for reselection on an annual basis during the term of its compact. The Board emphasized the need for all partner countries to maintain or improve their policy performance. If it is determined that a country has demonstrated a significant policy reversal, MCC can hold it accountable by applying MCC's Suspension and Termination Policy (*www.mcc.gov/pages/about/policy/policy-on-suspension-and-termination*).

Regional partnerships

The Board also confirmed its support for MCC's efforts to explore new partnerships in South Asia that could contribute to regional economic benefits. This is because, under the right circumstances, such a regional approach may present opportunities to take advantage of higher rates of return on investment and/or larger-scale reductions in poverty.

[FR Doc. 2014–29567 Filed 12–16–14; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

Alan T. Waterman Award Committee; 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: Alan T. Waterman Award Committee (1172).

Date and Time: January 8, 2015, 8:30 a.m.–2:00 p.m.

Place: NSF, 4201 Wilson Blvd., Room 1295, Arlington, Virginia 22230.

Type of Meeting: Closed.

Contact Person: Ms. Mayra Montrose, Program Manager, Room 1282, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230; Telephone: 703–292–8040.

Purpose of Meeting: To provide advice and recommendations in the selection of the Alan T. Waterman Award recipient.

Agenda: To review and evaluate nominations as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: December 12, 2014.

Suzanne Plimpton,

Acting, Committee Management Officer.

[FR Doc. 2014–29553 Filed 12–16–14; 8:45 am]

BILLING CODE 7555–01–P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee; Open Committee Meetings; Correction

AGENCY: U.S. Office of Personnel Management.

ACTION: Notice, correction.

SUMMARY: The U.S. Office of Personnel Management (OPM) published a notice in the **Federal Register** on December 8, 2014, (79 FR 72714) announcing the 2015 meeting dates of the Federal Prevailing Rate Advisory Committee. The notice incorrectly listed the year of the meetings. This document corrects this error.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, by telephone at (202) 606–2858 or by email at *pay-leave-policy@opm.gov.*

Correction: The correct dates are as follows:

Thursday, January 15, 2015
Thursday, February 19, 2015
Thursday, March 19, 2015
Thursday, April 16, 2015
Thursday, May 21, 2015
Thursday, June 18, 2015
Thursday, July 16, 2015
Thursday, August 20, 2015
Thursday, September 17, 2015
Thursday October 15, 2015
Thursday, November 19, 2015
Thursday, December 17, 2015

U.S. Office of Personnel Management.

Sheldon Friedman,

Chairman, Federal Prevailing Rate Advisory Committee.

[FR Doc. 2014–29447 Filed 12–16–14; 8:45 am]

BILLING CODE 6325–49–P

OFFICE OF PERSONNEL MANAGEMENT

President's Commission on White House Fellowships Advisory Committee: Closed Meeting

AGENCY: President's Commission on White House Fellowships, U.S. Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The President's Commission on White House Fellowships (PCWHF) was established by an Executive Order in 1964. The PCWHF is an advisory committee composed of Special Government Employees appointed by the President. The Advisory Committee will meet in June to interview potential candidates for recommendation to become a White House Fellow.

The meeting is closed.

Name of Committee: President's Commission on White House Fellowships Mid-Year Meeting.

Date: January 26, 2015.

Time: 8:00 a.m.–5:30 p.m.

Place: TBD.

Agenda: The Commission will talk to current Fellows on how their placements are going and discuss progress on strategic goals and recruiting efforts.

Location: TBD.

FOR FURTHER INFORMATION CONTACT: Jennifer Y. Kaplan, 712 Jackson Place NW., Washington, DC 20503, and Phone: 202–395–4522.

President's Commission on White House Fellowships.

Jennifer Y. Kaplan,

Director.

[FR Doc. 2014–29556 Filed 12–16–14; 8:45 am]

BILLING CODE 6325–44–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–15 and CP2015–19; Order No. 2283]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Express Contract 22 negotiated service agreement to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 18, 2014.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 22 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

[1] Request of the United States Postal Service to Add Priority Mail Express Contract 22 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, December 9, 2014 (Request).

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–15 and CP2015–19 to consider the Request pertaining to the proposed Priority Mail Express Contract 22 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than December 18, 2014. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lydudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–15 and CP2015–19 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Lydudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than December 18, 2014.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2014–29461 Filed 12–16–14; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* December 17, 2014.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 11, 2014, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 104 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–19, CP2015–23.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2014–29477 Filed 12–16–14; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:
Form F–6;
SEC File No. 270–270, OMB Control No. 3235–0292.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form F–6 (17 CFR 239.36) is a form used by foreign companies to register the offer and sale of American Depositary Receipts (ADRs) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). Form F–6 requires disclosure of information regarding the terms of the depository bank, fees charged, and a description of the ADRs. No special information regarding the foreign company is required to be prepared or disclosed, although the foreign company must be one which periodically furnishes information to the Commission. The information is needed to ensure that investors in ADRs have full disclosure of information concerning the deposit agreement and the foreign company. Form F–6 takes approximately 1.35 hour per response to prepare and is filed by 525 respondents annually. We estimate that 25% of the 1.35 hour per response (0.338 hours) is prepared by the filer for a total annual reporting burden of 177 hours (0.338 hours per response x 525 responses).

The information provided on Form F–6 is mandatory to best ensure full disclosure of ADRs being issued in the U.S. All information provided to the

Commission is available for public review upon request.

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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Acting Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: December 11, 2014.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29515 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA, 100 F Street NE., Washington, DC 20549–2736.

Extension: Form 15;
OMB Control No. 3235–0167, SEC File No. 270–170.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget the request for extension of the previously approved collection of information discussed below.

Form 15 (17 CFR 249.323) is a certification of termination of a class of security under Section 12(g) or notice of suspension of duty to file reports pursuant to Sections 13 and 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). All information is provided to the public for review. We estimate that approximately 811 issuers file Form 15 annually and it takes approximately 1.5 hours per response to prepare for a total of 1,217 annual burden hours.

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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: December 11, 2014.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29514 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street, NE., Washington, DC 20549–2736

Extension:
Rule 12g3–2;
SEC File No. 270–104, OMB Control No. 3235–0119.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Rule 12g3–2 (17 CFR 240.12g3–2) under the Securities Exchange Act of 1934 (the ''Exchange Act'') provides an exemption from Section 12(g) of the Exchange Act (15 U.S.C. 78l(g)) for foreign private issuers. Rule 12g3–2 is designed to provide investors in foreign securities with information about such securities and the foreign issuer. As a condition to the exemption, a non-Exchange Act reporting foreign private issuer must publish in English specified non-U.S. disclosure documents required by Rule 12g3–2(b) for its most recently completed fiscal year on its Internet Web site or through an electronic information delivery system in its primary trading market. In addition, the rule requires a foreign private issuer similarly to publish electronically specified non-U.S. disclosure documents in English on an ongoing basis for subsequent fiscal years as a condition to maintaining the Rule 12g3–2(b) exemption. We estimate that approximately 1,386 respondents claim the exemption. Each respondent publishes an estimated 12 submissions pursuant to Rule 12g3–2 per year for a total of 16,632 responses. We estimate the number of burden hours incurred by foreign private issuers to produce the Rule 12g3–2(b) publications to total 37,206, or approximately 2.237 burden hours per response (2.237 hours per response x 16,632 responses).

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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon,100 F Street, NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: December 11, 2014.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29516 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension: Form 4;
SEC File No. 270–126, OMB Control

No. 3235–0287.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Under the Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) every person who is directly or indirectly the beneficial owner of more than 10 percent of any class of any equity security (other than an exempted security) which registered under Section 12 of the Exchange Act (15 U.S.C. 78*l*), or who is a director or any officer of the issuer of such security (collectively ''insider), must file a statement with the Commission reporting their ownership. Form 4 is a statement to disclose changes in an insider's ownership of securities. The information is used for the purpose of disclosing the equity holdings of insiders of reporting companies. Approximately 204,054 insiders file Form 4 annually and it takes approximately 0.5 hours to prepare for a total of 102,027 annual burden hours.

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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov*; and (ii) Pamela Dyson, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: December 11, 2014.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29513 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension: Form 3;

SEC File No. 270–125, OMB Control No. 3235–0104.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Under the Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) every person who is directly or indirectly the beneficial owner of more than 10 percent of any class of any equity security (other than an exempted security) which registered under Section 12 of the Exchange Act (15 U.S.C. 78l), or who is a director or an officer of the issuer of such security (collectively ''insiders''), must file statement with the Commission reporting their ownership. Form 3 (17 CFR 249.103) is an initial statement of beneficial ownership of securities. Approximately 16,855 insiders file Form 3 annually and it takes approximately 0.5 hours to prepare for a total of 8,428 annual burden hours.

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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov*. Comments must be submitted to OMB within 30 days of this notice.

Dated: December 11, 2014.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29512 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31369; 812–14093]

Morgan Creek Global Equity Long/Short Institutional Fund, et al.; Notice of Application

December 11, 2014.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(c) and 18(i) of the Act and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares (''Classes'') with varying sales loads and to impose asset-based service and/or distribution fees and contingent deferred sales loads (''CDSCs'').

Applicants: Morgan Creek Global Equity Long/Short Institutional Fund (the ''Fund''), Morgan Creek Capital Management, LLC (the ''Adviser'') and Town Hall Capital, LLC (the ''Distributor'').

DATES: *Filing Dates:* The application was filed on November 15, 2012, and amended on April 18, 2013, April 11, 2014, August 13, 2014 and November 21, 2014.

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 January 5, 2015, and should be accompanied by proof of service on the 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: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants, c/o David James, State Street Bank and Trust Company, 4 Copley Place, 5th Floor, Mail Stop CPH 0326, Boston, MA 02116.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551–6990 or Mary Kay Frech, 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 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 Fund is a continuously offered non-diversified closed-end management investment company registered under the Act and organized as a Delaware statutory trust. The Adviser, a North Carolina limited liability company, is registered as an investment adviser under the Investment Advisers Act of 1940 and serves as investment adviser to the Fund. The Distributor, a broker-dealer registered under the Securities Exchange Act of 1934 (''1934 Act''), acts as principal underwriter of the Fund. The Distributor is under common control with the Adviser and is an affiliated person, as defined in section 2(a)(3) of the Act, of the Adviser.

2. The Fund continuously offers its shares pursuant to its currently effective registration statement under the Securities Act of 1933. The Fund's shares are not listed on any securities exchange and do not trade on an over-the-counter system such as Nasdaq. Applicants do not expect that any secondary market will develop for the Fund's shares.

3. The Fund currently issues a single class of shares (''Initial Class'') at net asset value per share (''NAV''). The Initial Class is not currently subject to any sales loads or distribution and/or service fees. The Fund proposes to offer additional Classes of shares that will adopt a distribution and service plan in compliance with rules 12b–1 and 17d–3 under the Act as if such rules applied to closed-end management investment companies (''Distribution and Service Plan''). Additional Classes may be subject to a sales load, a distribution fee (''Distribution Fee''), and/or a service fee (''Service Fee''), pursuant to the Distribution and Service Plan.[1]

4. In order to provide a limited degree of liquidity to shareholders, the Fund may from time to time offer to repurchase shares at their then-current NAV in accordance with rule 13e–4 under the 1934 Act pursuant to written tenders by shareholders. Repurchases of the Fund's shares are made at such times, in such amounts and on such terms as may be determined by the board of trustees of the Fund (''Board'') in its sole discretion. The Adviser ordinarily recommends that the Board authorize the Fund to offer to repurchase shares from shareholders quarterly.

5. Applicants request that the order also apply to any continuously-offered registered closed-end management investment company existing now or in the future for which the Adviser or the Distributor, or any entity controlling, controlled by, or under common control with the Adviser or the Distributor acts as investment adviser or principal underwriter, and which provides periodic liquidity with respect to its shares pursuant to rule 13e–4 under the 1934 Act (collectively with the Fund, the ''Funds'').[2]

6. Applicants represent that any asset-based Distribution and Service Fees will comply with the provisions of rule 2830(d) of the Conduct Rules of the National Association of Securities Dealers, Inc. (''NASD Conduct Rule 2830'').[3] Applicants also represent that the Fund will disclose in its prospectus, the fees, expenses and other characteristics of each Class offered for sale by the prospectus, as is required for open-end, multiple class funds under Form N–1A. As if it were an open-end management investment company, the Fund will disclose fund expenses in shareholder reports, and disclose in its prospectus any arrangements that result in breakpoints in, or elimination of, sales loads.[4] Applicants will also comply with any requirements that may be adopted by the Commission or FINRA regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements as if those requirements applied to the Fund and the Distributor.[5]

7. The Fund will allocate all expenses incurred by it among the various Classes based on net assets of the Fund attributable to each such Class, except that the NAV and expenses of each Class will reflect the expenses associated with the Distribution and Service Plan of that Class (if any), and any other incremental expenses of that Class (including transfer agency fees, if any). Expenses of the Fund allocated to a particular Class of the Fund's shares will be borne on a pro rata basis by each outstanding share of that Class. Applicants state that the Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

8. In the event the Funds impose a CDSC, applicants will comply with the provisions of rule 6c–10 under the Act, as if that rule applied to closed-end management investment companies. With respect to any waiver of, scheduled variation in, or elimination of the CDSC, the Fund will comply with the requirements of rule 22d–1 under the Act as if the Fund were an open-end investment company.

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple Classes of the Fund may be prohibited by section 18(c).

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that permitting multiple Classes of the Fund may violate section 18(i) of the Act because each Class would be entitled to

[1] The Fund will not impose an ''early withdrawal charge'' or ''repurchase fee'' on shareholders who purchase and tender their shares.

[2] Any Fund relying on this relief will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each investment company presently intending to rely on the requested order is listed as an applicant.

[3] Any references to NASD Conduct Rule 2830 include any successor or replacement Financial Industry Regulatory Authority Rule to NASD Conduct Rule 2830.

[4] See Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release).

[5] See Confirmation Requirements and Point of Sale Disclosure Requirements for Transactions in Certain Mutual Funds and Other Securities, and Other Confirmation Requirement Amendments, and Amendments to the Registration Form for Mutual Funds, Investment Company Act Release No. 26341 (Jan. 29, 2004) (proposing release).

exclusive voting rights with respect to matters solely related to that Class.

3. Section 6(c) 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 provision of the Act, or from any rule under the Act, if and to the extent 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. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Fund to issue multiple Classes.

4. Applicants submit that the proposed allocation of expenses and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed system would permit the Fund to facilitate the distribution of Classes through diverse distribution channels and would provide investors with a broader choice of shareholder options. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state the Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

CDSCs

5. Applicants believe that the requested relief meets the standards of section 6(c) of the Act. Rule 6c–10 under the Act permits open-end investment companies to impose CDSCs, subject to certain conditions. Applicants state that the Fund does not anticipate imposing CDSCs and would only do so in compliance with rule 6c–10 under the Act as if that rule were applied to closed-end investment companies. The Fund also will make all required disclosures in accordance with the requirements of Form N–1A concerning CDSCs. Applicants further state that, in the event the Fund imposes CDSCs, the Fund will apply the CDSCs (and any waivers or scheduled variations of the CDSCs) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act.

Asset-Based Service and/or Distribution Fees

6. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in which such registered company is a joint or a joint and several participant unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

7. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to permit the Fund to impose Distribution Fees and/or Service Fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Applicants will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3 and 22d–1 under the Act, as amended from time to time or replaced, as if those rules applied to closed-end management investment companies, and will comply with the NASD Conduct Rule 2830, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29500 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31372; File No. 812–14333]

ACAP Strategic Fund and SilverBay Capital Management LLC; Notice of Application

December 11, 2014.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(c) and 18(i) of the Act, under sections 6(c) and 23(c)(3) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based distribution fees and early withdrawal charges (''EWCs'').

Applicants: ACAP Strategic Fund (''Initial Fund'') and SilverBay Capital Management LLC (''Adviser'').

DATES: *Filing Dates:* The application was filed on July 15, 2014, and amended on November 5, 2014 and December 8, 2014.

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 January 5, 2015 and should be accompanied by proof of service on the 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: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: 350 Madison Avenue, 9th Floor, New York, NY 10017.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Counsel, at (202) 551–6812, 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 Initial Fund is a Delaware statutory trust that is registered under the Act as a non-diversified, closed-end management investment company. The Initial Fund's investment objective is to achieve maximum capital appreciation. The Initial Fund pursues this objective by investing its assets primarily in equity securities of U.S. and foreign companies that the Adviser believes are well positioned to benefit from demand for their products or services, including companies that can innovate or grow rapidly relative to their peers in their markets. The Initial Fund also pursues its objective by effecting short sales of securities when the Adviser believes that the market price of a security is above its estimated intrinsic or fundamental value.

2. The Adviser is a Delaware limited liability company and is registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser serves as investment adviser to the Initial Fund.

3. Applicants seek an order to permit the Initial Fund to issue multiple classes of shares, each having its own fee and expense structure, and to impose EWCs and asset-based distribution fees with respect to certain classes.

4. Applicants request that the order also apply to any continuously-offered registered closed-end management investment company that has been previously organized or that may be organized in the future for which the Adviser or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,[1] acts as investment adviser and which operates as an interval fund pursuant to rule 23c–3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Securities Exchange Act of 1934 (''Exchange Act'') (each a ''Future Fund,'' and together with the Initial Fund, the ''Funds'').[2]

5. The Initial Fund is currently making a continuous public offering of its common shares following the effectiveness of its initial registration statement. Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange nor quoted on any inter-dealer quotation system. Applicants do not expect there to be a secondary trading market for shares of the Funds. The minimum initial investment in the Initial Fund by an investor is $100,000, subject to reduction at the discretion of an investor's broker, dealer, or other financial intermediary, but not below $50,000. Shares of the Initial Fund may be purchased only by investors who certify to the Initial Fund or its agents that they have a net worth (in the case of a natural person or with assets held jointly with a spouse) of more than $2 million, excluding the value of the primary residence of such person and any debt secured by such property (up to the current market value of the residence).

6. If the requested relief is granted, the Initial Fund intends to redesignate its common shares as ''Class A Shares'' and anticipates commencing a continuous offering of Class W Shares. The Initial Fund's Class A Shares will be subject to a front-end sales load based on the amount invested and will also be subject to a shareholder servicing fee and other expenses. The Initial Fund's Class W Shares will be subject to other expenses, but will not be subject to an asset-based distribution fee. Currently, Class A Shares and Class W Shares will not be subject to an EWC. However, applicants state that Class A Shares and other classes may, in the future, be subject to an EWC. Shares that are not subject to an EWC when purchased will not subsequently be subject to an EWC.

7. Applicants state that, from time to time, the Initial Fund may create additional classes of shares, the terms of which may differ from the Class A and Class W Shares in the following respects: (i) The amount of fees permitted by different distribution plans; (ii) voting rights with respect to a distribution plan of a class; (iii) different class designations; (iv) the impact of any class expenses directly attributable to a particular class of shares allocated on a class basis as described in the application; (v) any differences in dividends and net asset value resulting from differences in fees under a distribution plan or in class expenses; (vi) any EWC or other sales load structure; and (vii) exchange or conversion privileges of the classes as permitted under the Act.

8. Applicants state that the Initial Fund has adopted a fundamental policy to repurchase a specified percentage of its shares (no less than 5%) at net asset value on a quarterly basis. Such repurchase offers will be conducted pursuant to rule 23c–3 under the Act. Each of the other Funds will likewise adopt fundamental investment policies in compliance with rule 23c–3 and make quarterly repurchase offers to its shareholders or provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act.[3] Any repurchase offers made by the Funds will be made to all holders of shares of each such Fund.

9. Applicants represent that any asset-based service and distribution fees for each class of shares will comply with the provisions of NASD Rule 2830(d) (''NASD Sales Charge Rule'').[4] Applicants also represent that each Fund will disclose in its prospectus the fees, expenses and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multiple class funds under Form N–1A. As is required for open-end funds, each Fund will disclose its expenses in shareholder reports, and disclose any arrangements that result in breakpoints in or elimination of sales loads in its prospectus.[5] In addition, applicants will comply with applicable enhanced fee disclosure requirements for funds of funds, including registered funds of hedge funds.[6]

10. Each of the Funds will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to the Fund. In addition, each Fund will contractually require that any distributor of the Fund's shares comply

[1] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Any Fund relying on this relief in the future will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each entity presently intending to rely on the requested relief is listed as an applicant.

[3] Applicants submit that rule 23c–3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to Rule 415 under the Securities Act of 1933.

[4] Any reference to the NASD Sales Charge Rule includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority (''FINRA'').

[5] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[6] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). See also Rules 12d1–1, *et seq.* of the Act.

with such requirements in connection with the distribution of such Fund's shares.

11. Each Fund will allocate all expenses incurred by it among the various classes of shares based on the net assets of the Fund attributable to each class, except that the net asset value and expenses of each class will reflect distribution fees, service fees, and any other incremental expenses of that class. Expenses of the Fund allocated to a particular class of shares will be borne on a pro rata basis by each outstanding share of that class. Applicants state that each Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

12. Applicants state that each Fund may impose an EWC on shares submitted for repurchase that have been held less than a specified period and may waive the EWC for certain categories of shareholders or transactions to be established from time to time. Applicants state that each of the Funds will apply the EWC (and any waivers or scheduled variations of the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Funds were open-end investment companies.

13. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with the Fund's periodic repurchase offers, exchange their shares of the Fund for shares of the same class of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, ''Other Funds''). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3, each Fund will treat an EWC as if it were a contingent deferred sales load (''CDSL'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of shares of the Funds may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

3. Section 6(c) 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 provision of the Act, or from any rule thereunder, if and to the extent 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. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Funds to issue multiple classes of shares.

4. Applicants submit that the proposed allocation of expenses and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its shares and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company will purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment company (an ''interval fund'') to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act provides that an interval fund may deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for the Funds to impose EWCs on shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. The Funds will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSLs. Applicants further state that the Funds will apply the EWC (and any waivers or scheduled variations of the EWC) uniformly to all shareholders in a given class and consistently with the

requirements of rule 22d–1 under the Act.

Asset-Based Distribution Fees

1. Section 17(d) of the Act prohibits an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates in contravention of Commission regulations. Rule 17d–1 provides that no joint transaction covered by the rule may be effected unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Fund to impose asset-based distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based distribution fees.

For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' institution of asset-based distribution fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants. Applicants therefore believe that the requested relief meets the standards of section 6(c) of the Act.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the NASD Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29501 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73813; File No. SR–BATS–2014–063]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

December 11, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2014, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its fee schedule effective immediately in order to adopt pricing for ROOC orders, to adopt pricing for orders that execute pursuant to Rule 11.24, titled ''Opening Process for Non-BATS-Listed Securities,'' to adjust the requirements to achieve Tier 3 of the Cross-Asset Step-Up Tiers, and to amend pricing for and add two additional tiers to the NBBO Setter program, as described below.

ROOC

The Exchange recently filed a rule change to adopt a new routing strategy, ROOC, which provides that orders entered on the Exchange may be designated for participation in the opening, re-opening (following a halt suspension or pause), or closing process (collectively, an ''Auction'') of a primary listing market other than the Exchange if received before the opening/re-

[5] A Member is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

opening/closing time of such market.[6] As such, the Exchange proposes to adopt pricing related to this new routing strategy: The Exchange is proposing to charge $0.0015 per share for ROOC orders routed and executed in the listing market's opening or re-opening cross and charge $0.0010 per share for orders routed and executed in the listing market's closing process.

Opening Process

The Exchange recently filed and the Commission approved a proposed rule change to adopt Rule 11.24, establishing an opening and re-opening process on the Exchange in non-BATS-listed securities (the ''Opening Process'').[7] The Opening Process is substantially similar to the opening processes on EDGA Exchange, Inc. (''EDGA'') and EDGX Exchange, Inc. (''EDGX''). The Exchange proposes to adopt pricing for the new Opening Process such that any non-BATS-listed security that is executed in the Opening Process will be charged $0.0005 per share.[8]

Cross-Asset Step-Up Tiers

Currently, a Member receives a $0.0032 rebate per share when they achieve Tier 3 of the Cross-Asset Step-Up Tier, which requires that the Member's Step-Up Add TCV [9] to be equal to or greater than 0.30% (''Requirement One'') and that the Member's Options Step-Up Add TCV [10] is equal to or greater than 0.40% (''Requirement Two''). There is no minimum that a Member's Step-Up Add TCV must meet in order to achieve Cross-Asset Step-Up Tiers 1 and 2. The Exchange is proposing to amend Requirement One in order to change the measurement from a Member's Step-Up Add TCV to a Member's ADAV [11] as a percentage of TCV [12] and to lower the threshold required to satisfy Requirement One from 0.30% to 0.20%. This means that a Member would fulfill Requirement One by achieving where the Member's ADAV as a percentage of TCV is greater than 0.20%. This proposed change would make Requirement One significantly easier for Members to meet, not only because the numerical threshold has been lowered from 0.30% to 0.20%, but also because the entirety of a Member's monthly ADAV would be included in the calculation (ADAV/TCV) instead of only including the increase in the Member's ADAV as a percentage of TCV for the current month as compared to January 2014, as is currently the case ([ADAV/TCV]–[ADAV in January 2014/TCV in January 2014]). In coordination with lowering the threshold for Requirement One, the Exchange is also proposing to increase the threshold for meeting Requirement Two by requiring a Member's Options Step-Up Add TCV to be equal to or greater than 0.60% instead of 0.40%. The Exchange believes that the combination of these two proposed changes will allow more Members to meet Requirement One, which will incentivize a greater number of Members to seek to meet Requirement Two, thereby enhancing liquidity on both the Exchange and the Exchange's options platform (''BATS Options'') and providing more Members with the opportunity to receive enhanced rebates.

NBBO Setter

Currently, the Exchange only offers a single NBBO Setter rebate, which provides that an order that establishes a new NBBO receives an additional rebate of $0.0002 per share, and a single NBBO Joiner rebate, which provides that any order that joins the NBBO when BATS is not already at the NBBO receives an additional rebate of $0.0001 per share. The Exchange is proposing to add two additional tiers at which Members may receive additional rebates for setting the NBBO and to amend the rebate per share associated with both the current NBBO Setter rebate and the NBBO Joiner rebate. In conjunction with the addition of these two new tiers, the Exchange is proposing to add additional language to footnote one on the fee schedule in order to establish the definition of Setter Add TCV as meaning the average daily added volume calculated as the number of displayed shares added that establish a new NBBO as a percentage of TCV.

First, the Exchange is proposing to add an NBBO Setter Tier 2 and NBBO Setter Tier 3, as well as changing the existing NBBO Setter rebate to NBBO Setter Tier 1. The Exchange is proposing that NBBO Setter Tier 2 shall state that any order that establishes a new NBBO and the Member's Setter Add TCV is equal to or greater than 0.05% shall receive an additional rebate of $0.0002 per share. The Exchange is also proposing that NBBO Setter Tier 3 shall state that any order establishing a new NBBO where such Member's Setter Add TCV is equal to or greater than 0.10% shall receive an additional rebate of $0.0004 per share. Finally, the Exchange is proposing to change the rebate for NBBO Setter Tier 1 to $0.0001 per share and the NBBO Joiner rebate to $0.00005 per share.

The Exchange proposes to implement the amendments to its fee schedule effective immediately.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[13] Specifically, the Exchange believes that the proposed rule change is consistent with Sections 6(b)(4) of the Act and 6(b)(5) of the Act,[14] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive.

The Exchange believes that the proposed changes to the Exchange's fee schedule to add fees for the ROOC routing strategy when routed and executed in the listing market's Auction represent a reasonable and equitable allocation of fees because they are equal to or roughly equivalent to the fees that will be charged pursuant to the applicable exchange's fee schedule for participation in an Auction. The Exchange further believes that the proposed fees for ROOC are non-discriminatory because they apply uniformly to all Members and, again, because they approximate the fees at the away venue.

[6] *See* Securities Exchange Act Release No. 73418 [sic.] (October 23, 2014), 79 FR 64431 (October 29, 2014) (SR–BATS–2014–052).

[7] *See* Securities Exchange Act Release No. 73473 (October 30, 2014), 79 FR 65744 (November 5, 2014) (SR–BATS–2014–037).

[8] The Exchange notes that this proposed fee is $0.0005 less than the fee charged for executions in the opening process on EDGX.

[9] ''Step-Up Add TCV'' means ADAV as a percentage of TCV in January 2014 subtracted from current ADAV as a percentage of TCV.

[10] ''Options Step-Up Add TCV'' means ADAV as a percentage of TCV in January 2014 subtracted from current ADAV as a percentage of TCV, using the definitions of ADAV and TCV as provided under Options Pricing.

[11] ''ADAV'' means average daily added volume calculated as the number of shares added.

[12] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption, on any day with a scheduled early market close and the Russell Reconstitution Day.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4) and (5).

The Exchange also believes that its proposed pricing for the Opening Process is reasonable and equitable because the Opening Process is generally analogous to the opening and halt auctions in BATS-listed securities (the ''Opening Auctions'') in that they both allow orders to queue for participation at the market open or to roll over into the continuous book and the proposed fees are equal to the standard fees applicable to orders that participate in the Opening Auctions. Further, the fee per share for participation in the Opening Process is $0.0005 less than the fee charged for executions in the opening process on EDGX. The Exchange also believes that the proposed fees for the Opening Process are non-discriminatory because they apply uniformly to all Members and, again, because they are equal to or less the fees charged at other venues for analogous executions.

The Exchange also believes that its proposed additional tiers and associated rebates to the NBBO Setter are reasonable and equitable because the tiers based on Setter Add TCV is intended to reward those Members that [sic.] and incentivize other Members to add a larger amount of volume that sets the NBBO on the Exchange by providing additional rebates of $0.0002 and $0.0004 per share for Members that have a Setter Add TCV of 0.05% and 0.10%, respectively. Further, the Exchange believes that the new NBBO Setter tiers are reasonable and equitable because they incentivize and reward Members for posting liquidity that sets the NBBO on the Exchange, which is consistent with the overall goals of enhancing market quality on the Exchange. The Exchange also believes that the proposed rebates associated with these tiers are non-discriminatory in that they are equally available to all Members and, again, because they are consistent with the goal of enhancing market quality on the Exchange.

Similarly, the Exchange believes that the reductions to the NBBO Setter Tier 1 and NBBO Joiner rebates are reasonable and equitable because, while they mark reductions to the standard additional rebates, Members have the opportunity to receive equal or greater rebates through the addition of NBBO Setter Tier 2, which allows Members to receive the old NBBO Setter Tier 1 rebate ($0.0002) if they achieve a modest Setter Add TCV (0.05%), and the addition of NBBO Setter Tier 3, which allows Members to potentially receive $0.0004 per share where the Member achieves NBBO Setter Tier 3 (0.10% Setter Add TCV). Further, because the Exchange is lowering the NBBO Setter Tier 1 rebate to $0.0001 per share, it follows that the NBBO Joiner rebate should be reduced to an amount less than $0.0001 because NBBO Joiner liquidity is providing less value to the broader market and the Exchange by only joining the already established NBBO than an order that sets the NBBO for the entire market. The Exchange believes that such proposed fee changes for NBBO Setter Tier 1 and NBBO Joiner are non-discriminatory because they will apply uniformly to all Members and all Members will still have the opportunity to achieve the higher rebates by achieving the requirements to meet NBBO Setter Tiers 2 and 3.

Finally, the Exchange believes that the proposed changes to the Cross-Asset Step-Up Tier 3 are reasonable and equitable because the threshold for achieving Requirement One is being significantly reduced by: (i) Adjusting the calculation to include only ADAV as a percentage of TCV from the current month instead of ADAV as a percentage of TCV from the current month minus ADAV as a percentage of TCV in January of 2014; and (ii) by reducing the required percentage from 0.30% to 0.20%, both of which combined will make it easier for Members to satisfy Requirement One. While the proposed changes in Requirement Two to the Options Step-Up TCV threshold will mark an increase in the Options Step-Up TCV necessary to satisfy Requirement Two, the Exchange believes that this proposal is reasonable and equitable when evaluated in conjunction with the relaxation of Requirement One. Specifically, the Exchange believes that the relaxation of Requirement One will generally make Tier 3 more attainable to more Members and will incentivize Members that otherwise would not have been eligible for Tier 3 to add more liquidity to both the Exchange and BATS Options, thereby improving market quality on both markets. The Exchange believes that these proposed amendments to Cross-Asset Step-Up Tier 3 are non-discriminatory in that they apply uniformly to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. To the contrary, the Exchange believes that the proposed changes will allow the Exchange to compete more ably with other execution venues by providing additional competitive services (ROOC, Opening Process) at competitive prices as well as to amend its fee schedule to increase the market quality in securities traded on the Exchange, thereby making it a more desirable destination venue for its customers. Also, because the market for order execution is extremely competitive, Members may readily opt to disfavor the Exchange's routing services if they believe that alternatives offer them better value. For orders routed through ROOC, the proposed fees approximate the cost to the Exchange of executing the orders on away trading venues. As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if the deem fee structures to be unreasonable or excessive.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f)(2) of Rule 19b–4 thereunder.[16] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(2).

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–BATS–2014–063 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2014–063. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2014–063 and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73816; File No. SR–NYSE–2014–64]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Proposes To Establish an Access Fee for the NYSE Best Quote & Trades Data Feed, Operative on December 1, 2014

December 11, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 26, 2014, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish an access fee for the NYSE Best Quote & Trades (''NYSE BQT'') data feed, operative on December 1, 2014. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to establish an access fee for the NYSE BQT data feed, effective December 1, 2014. The proposed fee for NYSE BQT would be $1,000 a month, provided that the market data recipient separately subscribes to and pays for the six existing market data products underlying the NYSE BQT data feed, consistent with the existing fee structures for those market data products.

The NYSE BQT data feed provides best bid and offer (''BBO'') and last sale information for the Exchange and its affiliates, NYSE Arca Equities, Inc. (''NYSE Arca'') and NYSE MKT LLC (''NYSE MKT'').[3] Specifically, the NYSE BQT data feed consists of certain data elements from six market data feeds—NYSE Trades, NYSE BBO, NYSE Arca Trades, NYSE Arca BBO, NYSE MKT Trades, and NYSE MKT BBO.[4] The NYSE BQT data feed has three channels: one channel for the last sale data (the ''last sale channel''), another channel for the BBO data (the ''best quotes channel''), and a third channel for consolidated volume data (the ''consolidated volume channel'').

The Exchange, NYSE Arca, and NYSE MKT are the exclusive distributors of the six BBO and Trades feeds from which certain data elements are taken to create the NYSE BQT. By contrast, the Exchange would not be the exclusive distributor of the aggregated and consolidated information that comprises the NYSE BQT data feed. Any entity that receives, or elects to receive, the six underlying data feeds would be able, if it so chooses, to create a data feed with the same information included in NYSE BQT and sell and distribute it to its clients so that it could be received by

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–73553 (Nov. 6, 2014), 79 FR 67491 (Nov. 13, 2014) (SR–NYSE–2014–40) (''NYSE BQT Approval Order'').

[4] These data feeds are offered pursuant to preexisting and effective rules and fees filed with the Securities and Exchange Commission (''Commission''). This filing does not affect those rules or the fees associated with these underlying data feeds or the ability for the Exchange, NYSE Arca, or NYSE MKT to amend the data feeds or fees associated with those data feeds pursuant to a separate rule filing. For NYSE Trades, *see* Securities Exchange Act Release Nos. 59290 (Jan. 23, 2009), 74 FR 5707 (Jan. 30, 2009) (SR–NYSE–2009–05) *and* 59606 (Mar. 19, 2009), 74 FR 13293 (Mar. 26, 2009) (SR–NYSE–2009–04). For NYSE BBO, *see* Securities Exchange Act Release No. 62181 (May 26, 2010), 75 FR 31488 (June 3, 2010) (SR–NYSE–2010–30). For NYSE Arca Trades, *see* Securities Exchange Act Release Nos. 59289 (Jan. 23, 2009), 74 FR 5711 (Jan. 30, 2009) (SR–NYSEArca–2009–06) *and* 59598 (Mar. 18, 2009), 74 FR 12919 (Mar. 25, 2009) (SR–NYSEArca–2009–05). For NYSE Arca BBO, *see* Securities Exchange Act Release No. 62188 (May 27, 2010), 75 FR 31484 (June 3, 2010) (SR–NYSEArca–2010–23). For NYSE MKT Trades and NYSE MKT BBO, *see* Securities Exchange Act Release No. 62187 (May 27, 2010), 75 FR 31500 (June 3, 2010) (SR–NYSEAmex–2010–35).

those clients as quickly as the NYSE BQT data feed would be received by those same clients.[5]

As proposed, the Exchange would charge a $1,000/month access fee for NYSE BQT, which reflects the value of the aggregation and consolidation function that the Exchange performs in creating NYSE BQT. To obtain NYSE BQT, the market data recipient would need to subscribe to and pay for the six data feeds underlying NYSE BQT consistent with the existing fee schedules for those market date products as previously filed with the Commission and which may be amended from time to time, including any applicable Access, Redistribution, Professional User, Non-Professional User, or Enterprise fees.[6] When subscribing to NYSE BQT, the underlying data feeds would be delivered in the NYSE BQT consolidated format, as described above, but charged for as if the recipient were receiving the underlying feeds directly. The Exchange notes that if a User chooses to receive the six underlying feeds both separately and in the NYSE BQT format, such User may be subject to additional Professional User or Non-Professional User fees to reflect the distribution of both NYSE BQT (which incorporates the six underlying data feeds) and any separate dissemination of the underlying data feeds. The Exchange believes that the proposed fees for NYSE BQT would not be lower than the cost to a vendor of creating a comparable product, including the cost of receiving the underlying data feeds.

The Exchange notes that another market participant seeking to distribute a competing product to NYSE BQT might engage in a different analysis of assessing the cost of a competing product, which may incorporate passing through fees associated with co-location at the Mahwah, New Jersey data center. However, the incremental co-location cost to a particular vendor might be inconsequential if such vendor is already co-located and is able to allocate its co-location costs over numerous product and customer relationships. The Exchange therefore believes that a vendor could create and offer a product similar to NYSE BQT on a cost-competitive basis.

The Exchange notes that the proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations or others would have in complying with the proposed rule change.

[5] *See* NYSE BQT Approval Order, *supra* note 4.

[6] *See supra* note 5.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[7] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[8] in particular, in that it provides an equitable allocation of reasonable fees among its members, issuers, and other persons using its facilities and is not designed to permit unfair discrimination among customers, issuers, brokers, or dealers. The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act[9] in that it is consistent with (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets; and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[10] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory.

The Exchange believes that the proposed $1,000/month access fee for NYSE BQT is reasonable because it represents the value for the data aggregation and consolidation function that the Exchange performs. The Exchange further believes that the proposed $1,000/month access fee is not designed to permit unfair discrimination because all market data recipients that would subscribe to NYSE BQT would be charged the same access fee.

The Exchange further believes that requiring market data recipients to separately subscribe to and pay for the six underlying data feeds to NYSE BQT is reasonable because by design, NYSE BQT represents an aggregated and consolidated version of those existing six data feeds. The Exchange notes that it is not seeking with this filing to establish fees relating to the underlying six BBO and Trades data feeds, as those fees have already been established consistent with Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(2)[12] thereunder, and which may be amended from time to time. However, the Exchange believes it would be unfair if it did not require NYSE BQT data feed recipients to separately subscribe to and pay for those six feeds because otherwise, NYSE BQT data feed recipients would be receiving a data product that includes such underlying data at a lower cost than separately subscribing to the underlying data feeds. Similarly, the Exchange believes that it would be reasonable to charge separate Professional User or Non-Professional User fees if a market data recipient chooses to receive both NYSE BQT and a separate dissemination of the six underlying data feeds in a non-consolidated form. The Exchange believes that such delivery would constitute two separate uses of the underlying data feeds and thus should be charged accordingly, consistent with the existing fee schedule for those market data products. The Exchange therefore believes that the proposed fee structure for NYSE BQT would not be lower than the cost to another party to create a comparable product, including the cost of receiving the underlying data feeds.

The Exchange notes that its proposed fee structure is similar to the fee structure for NLS Plus. NLS Plus is a data product that is offered by an affiliate of The NASDAQ Stock Market, Inc. (''NASDAQ'') that is not a self-regulatory organization. NLS Plus provides access to all NASDAQ OMX U.S. markets' last sale data as well as consolidated volume, including all trade data from NASDAQ, the FINRA/NASDAQ Trade Reporting Facility (''TRF''), NASDAQ OMX BX, and NASDAQ OMX PSX. NLS Plus also provides consolidated volume information as part of each trade message. To receive NLS Plus, the recipient must pay the fees for one or more NASDAQ underlying data feeds, plus an annual administrative fees attributable to each affiliated exchange.[13] In addition, BATS Global Markets (''BATS'') has announced that it intends to offer a market data product that provides a unified view of the aggregated best bid and offer, last sale, and optional depth information (five levels), including size, for all four equity exchanges operated by BATS.[14] The

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4), (5).

[9] 15 U.S.C. 78k–1.

[10] *See* 17 CFR 242.603.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

[13] The pricing for NLS Plus is available at *https://www.nasdaqtrader.com/Trader.aspx?id=nlsplus.* The applicable NASDAQ underlying data feeds for which a firm are be liable could be NASDAQ Last Sale (*See* NASDAQ Rule 7039) or NASDAQ Basic (*see* NASDAQ Rule 7047) market data products.

[14] *See http://cdn.batstrading.com/resources/press_releases/BATS-One-Announcement-FINAL.pdf.* BATS has also submitted rule filings to the Commission on behalf of its four exchanges to establish its proposed unified feed as a proprietary market data product. *See also* Securities Exchange Act Release Nos. 73594 (Nov. 14, 2014), 79 FR

Continued

Exchange believes that NYSE BQT will offer a competitive alternative to the NASDAQ product and the proposed BATS product.

The Exchange further believes that the proposed NYSE BQT fee structure is equitable and not unfairly discriminatory because all vendors and subscribers that elect to purchase NYSE BQT would be charged the same fees. In addition, vendors and subscribers that do not wish to purchase NYSE BQT may separately purchase the six individual underlying products, and if they so choose, perform a similar aggregation and consolidation function that the Exchange performs in creating NYSE BQT. To enable such competition, the Exchange is offering NYSE BQT on terms that a subscriber of those six feeds could offer a competing product if it so chooses.

The Exchange also notes that the use of NYSE BQT is entirely optional. Firms have a wide variety of alternative market data products from which to choose, including the exchanges' own underlying data products, the NASDAQ and BATS proprietary data products described in this filing, and consolidated data. Moreover, the Exchange is not required to make any proprietary data products available or to offer any specific pricing alternatives to any customers.

In addition, the fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to these data products further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives. That is, the Exchange competes with other exchanges (and their affiliates) that provide similar ''best quote and trade'' market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute NYSE BQT, prospective users likely would not subscribe to, or would cease subscribing to, NYSE BQT. In addition, the Exchange would compete with unaffiliated market data vendors who would be in a position to consolidate and distribute the same data that comprises the NYSE BQT feed into the vendor's own comparable market data product. If the third-party vendor is able to provide the exact same data for a lower cost, prospective users would avail themselves of that lower cost and elect not to take NYSE BQT.

The Exchange notes that the Commission is not required to undertake a cost-of-service or ratemaking approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would be so complicated that it could not be done practically.[15]

For these reasons, the Exchange believes that the proposed fees are reasonable, equitable, and not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[16] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the NYSE BQT data feed represents aggregated and consolidated information of six existing market data feeds. Although the Exchange, NYSE Arca, and NYSE MKT are the exclusive distributors of the six BBO and Trades feeds from which certain data elements are taken to create the NYSE BQT, the Exchange may not be the exclusive distributor of the aggregated and consolidated information that comprises the NYSE BQT data feed. Any other market data recipient of the six BBO and Trades feeds would be able, if they chose, to create a data feed with the same information as the NYSE BQT and distribute it to their clients on a level-playing field with respect to latency and cost as compared to the Exchange's product.[17]

The Exchange further believes that the proposed monthly access fee the Exchange proposes to charge clients for NYSE BQT would be pro-competitive because another market data recipient could perform a similar aggregating and consolidating function and similarly charge for such service. The Exchange notes that a competing vendor might engage in a different analysis of assessing the cost of a competing product, which may incorporate passing through fees associated with co-location at the Mahwah, New Jersey data center. However, the incremental co-location costs to a particular vendor may be inconsequential if such vendor is already co-located and is able to allocate its co-location costs over numerous product and customer relationships. The Exchange therefore believes that a competing vendor could create and offer a product similar to the NYSE BQT data feed at a similar cost. For these reasons, the Exchange believes that vendors could readily offer a product similar to NYSE BQT on a competitive basis.

Finally, the Exchange notes that there is already actual competition for products similar to NYSE BQT. NASDAQ already offers NASDAQ Basic, a filed market data product, and through its affiliate, offers NLS Plus, which provides a unified view of last trade information similar to NYSE BQT. In addition, BATS has recently filed to adopt a similar market data product.[18] The existence of these competing data products demonstrates that there is ample, existing competition for products such as NYSE BQT and the fees associated with such products are constrained by that competition.

As such, in establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all users. The existence of alternatives to NYSE BQT, including the six underlying feeds, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are

69142 (Nov. 20, 2014) (SR–BATS–2014–055); 73595 (Nov. 14, 2014), 79 FR 69160 (Nov. 20, 2014) (SR–BYX–2014–030); 73596 (Nov. 14, 2014), 79 FR 69148 (Nov. 20, 2014) (SR–EDGA–2014–25); and 73597 (Nov. 14, 2014), 79 FR 69180 (Nov. 20, 2014) (SR–EDGX–2014–25).

[15] The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties, including the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. *See* Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at *http://www.sec.gov/rules/concept/s72899/buck1.htm.*

[16] 78 U.S.C. 78f(b)(8).

[17] *See* NYSE BQT Approval Order, *supra* note 4.

[18] *See supra* note 15.

unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [19] and paragraph (f)(2) of Rule 19b–4 thereunder.[20] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2014–64 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2014–64. 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 NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2014–64 and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29494 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 240.19b–4(f)(2).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73814; File No. SR–CHX–2014–19]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Applicability of Certain Fees and Credits Provided Under the Fee Schedule

December 11, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1], and Rule 19b–4[2] thereunder, notice is hereby given that on December 4, 2014, the Chicago Stock Exchange, Inc. (''CHX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend the applicability of certain fees and credits provided under the Fee Schedule of the CHX (''Fee Schedule'') and to clarify other provisions throughout the Fee Schedule. The text of this proposed rule change is available on the Exchange's Web site at *(www.chx.com)* and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to expand the scope of Section E.1 of the Fee Schedule to include executions resulting from single-sided orders for securities that trade in Round Lots of less than 100 shares.[3] Moreover, the Exchange proposes to amend various provisions throughout the Fee Schedule for clarification and stylistic consistency. Aside from the proposed amendment of the scope of Section E.1, the Exchange does not propose to substantively modify any other fees, assessments, credits or rebates.

Proposed Elimination of Obsolete ''Effective'' and ''Operative'' Dates and Capitalization of Defined Terms

Initially, the Exchange proposes certain non-substantive global amendments to the Fee Schedule. Specifically, the Exchange proposes to delete references to obsolete ''effective'' and ''operative'' dates throughout the Fee Schedule, specifically found under:

- Sections B through E;

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.16b–4.

[3] CHX Article 1, Rule 2(f)(3) defines ''Round Lot'' as ''an order of 100 shares, unless otherwise determined by the Committee on Exchange Procedure.''

- Section J;
- Section L; and
- Sections O and P.

Similarly, the Exchange also proposes to eliminate obsolete language under Section D stating that ''no monthly charges will be assessed under this section D. for CHX's Equinix NY4 data center location under April 1, 2012.''

Moreover, the Exchange proposes to capitalize the terms ''Institutional Broker,'' ''Odd Lot,'' ''Round Lot'' and ''Clearing Participant'' throughout the Fee Schedule as they are defined terms under CHX Rules.[4] In addition, the Exchange proposes to delete the hyphen in between certain references to Odd Lots because the term, as defined under CHX Rules, does not contain a hyphen.[5] Specifically, the Exchange proposes to amend Section E.1(a), which includes a reference to Institutional Brokers; Sections E.3 and E.4, which include references to Odd Lots; Section E.8(a), which includes a reference to Round Lot; and Section F.2, which includes references to Institutional Broker and Clearing Participant.

Amended Section E.1

Section E.1 provides liquidity removing fees and liquidity providing credits for executions resulting from ''one-sided orders of 100+ shares,'' which describes a Round Lot or more for all but a handful of securities currently traded on the Exchange.[6] Thus, the Exchange does not currently apply Section E.1 fees and credits to executions resulting from orders in securities that trade in Round Lots of less than 100 shares. Instead, such executions are currently assessed fees pursuant to Section E.4, which apply to executions resulting from orders submitted as Odd Lots.[7]

In the interest of clarity and consistency, the Exchange proposes to expand the scope of Section E.1 to apply to executions ''resulting from orders submitted as at least a Round Lot,'' which would include securities that trade in Round Lots of less than 100 shares.[8] To this end, the Exchange proposes to amend the headline to Section E.1 by deleting the phrase ''single-sided order'' and replacing the phrase ''(one-sided orders of 100+ shares)'' with the phrase ''resulting from single-sided orders submitted as at least a Round Lot.'' Incidentally, the proposed headline clarifies that the Section E.1 fees and credits are assessed based on the size of the contra-side orders executed and not the size of the execution itself.[9] The proposed amended headline would state as follows:

Matching System executions resulting from single-sided orders submitted as at least a Round Lot

Moreover, the Exchange proposes the following clarifying and stylistic amendments to Section E.1:

- In the first full paragraph under Section E.1:
- Replace the phrase ''rebates paid'' with ''credits attributed'' to be consistent with the term ''liquidity providing credit'' utilized in the fees and credits chart;
- delete ''(Executions through an Institutional Broker Registered with the Exchange Under Article 17 (All Sessions)),'' as the Exchange proposes to amend the headline to Section E.3, as discussed below; and
- replace citation to ''Section E.3.a.'' with ''Section E.3(a)'' to be consistent with the existing taxonomical structure of the Fee Schedule, as described below in the proposed amendments to Section E.3.

Amended Section E.2–E.5 and E.7

The Exchange proposes to make additional clarifying and stylistic amendments to Section E. The Exchange proposes the following amendments to E.2:

- Amend the headline to Section E.2 to be stylistically consistent with the proposed amended headline to Section E.1 and to replace the term ''All Sessions'' with the more descriptive ''all trading sessions,'' which is a phrase currently used under the fees and credits chart of Section E.1. Thus, the proposed amended headline would state as follows:

Matching System executions resulting from two-sided orders (cross orders) of any number of shares (all trading sessions)[10]

The Exchange proposes the following amendments to Section E.3:

- Amend the headline to be stylistically consistent with the proposed amended headlines to Sections E.1 and E.2. Thus, the proposed amended headline would state as follows:

Matching System executions resulting from orders submitted by Institutional Brokers registered with the Exchange under Article 17 (all trading sessions)

- In the second to last paragraph under Section E.3:
- insert the term ''Section'' before ''E.4.,'' as the current citation is to Section E.4, and delete the period after ''E.4''; and
- replace ''see (1) and (2) above'' with the more accurate ''see Sections E.1 and E.2 above.''
- Replace paragraph ''a.'' and ''b.'' with ''(a)'' and ''(b),'' respectively, to be consistent with the existing taxonomical structure of the Fee Schedule, which utilizes parentheses to denote all subparagraphs under the first paragraph denoted by an Arabic numeral. Thus, the Exchange also proposes to amend Section E.3(b) to replace a citation to ''Section E.3.a.'' with ''Section E.3(a).''
- Under Section E.3(a), insert the number ''0'' in front of the period within ''$.003/share'' and after ''3'' and insert the term ''fee'' after ''$.003/share,'' so as to state ''$0.0030/share fee.''
- Under Section E.3(b), insert the number ''0'' in front of the period within ''$.0007/share'' and after ''7'' and insert the term ''fee'' after ''$.0007/share,'' so as to state ''$0.00070/share fee.''

The Exchange proposes the following amendments to Section E.4:

- Amend the headline to Section E.4 to be stylistically consistent with the proposed amended headlines to Sections E.1–3. Thus, the proposed amended headline would state as follows:

Matching System executions resulting from single-sided orders submitted as Odd Lots (all trading sessions)

- Insert the number ''0'' in front of the period within ''$.0040/share'' and insert the term ''fee'' after ''$.0040/share,'' so as to read ''$0.0040/share fee.''

The Exchange proposes to amend the headline to Section E.5 to replace ''All Sessions'' with the more descriptive and consistent ''all trading sessions.''

The Exchange proposes the following amendments to Section E.7:

- Amend the headline to replace the term ''All Sessions'' with the more

[4] *See* CHX Article 1, Rule 1(n) defining ''Institutional Broker;'' *see also* CHX Article 1, Rule 1(ee) defining ''Clearing Participant;'' *see also* CHX Article 1, Rule 2(f)(3) defining Round Lot; *see also* CHX Article 1, Rule 2(f)(2) defining ''Odd Lot.''

[5] *See* CHX Article 1, Rule 2(f)(2).

[6] As of the date of this filing, the Exchange permits the trading of ten securities in Round Lots of less than 100 shares, none of which have a primary listing on the Exchange. The Round Lot size for a security is determined by the Exchange and is identical to the round lot size set by the primary listing market.

[7] *See supra* note 5.

[8] *See supra* note 3; *see also supra* note 6.

[9] For example, where there is an execution between an incoming buy order submitted as an Odd Lot and a resting sell order submitted as a Round Lot, the buy side will be assessed fees pursuant to Section E.4 and the sell side will be given a credit pursuant to Section E.1.

[10] CHX Article 1, Rule 2(a)(2) defines ''cross order,'' in pertinent part, as ''an order to buy and sell the same security at a specific price better than the best bid and offer displayed in the Matching System and which would not constitute a trade-through under Reg NMS (including all applicable exceptions and exemptions).''

descriptive and consistent ''all trading sessions.''

• Insert the number ''0'' in front of the period within ''$.003/share'' and after ''3'' and insert the term ''fee'' after ''$.003/share,'' so as to read ''$0.0030/share fee.''

Amended Section F

The Exchange proposes the following clarifying and stylistic amendments to Section F:

• Under Section F.2, delete the period placed after reference to ''Section E.7'' to be consistent with the current taxonomical and related citation structure of the Fee Schedule.

• Under Section F.4, amend obsolete citations to various credits that are no longer offered by the Exchange. Currently, the only credits available pursuant to Section F are the Institutional Broker credits, described under current Section F.2. Thus, the Exchange proposes to replace all citations to specific paragraphs under Section F with citations to ''Section F.2'' only.[11]

Operative Date

The Exchange proposes to make all changes proposed herein operative *January 2, 2015.* Participants will be notified of the proposed changes pursuant to a Legal Notice that will be issued immediately after this proposed rule change is filed.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[12] in general, and furthers the objectives of Sections 6(b)(1)[13] and (b)(4)[14] of the Act, in particular. Specifically, the proposed amended Section E.1 will continue to apply equally to all Participants that submit single-sided orders to the Matching System, in furtherance of Sections 6(b)(4), as the proposed rule provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. Moreover, the Exchange believes that the proposed amended Section E.1 simplifies the Fee Schedule by applying to executions resulting from all Round Lot orders, as opposed to merely those that result from orders for 100 or more shares, and the other amendments to the Fee Schedule would provide clarity and stylistic consistency to the Fee Schedule, both in furtherance of Section 6(b)(1), as the proposed rule would better enable the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Act and to comply, and to enforce compliance by its Participants with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Given that the proposed amendment to Section E.1 would impact an extremely small number of securities traded on the Exchange and the proposed clarifying and stylistic amendments do not substantively modify the Fee Schedule, the proposed rule change would have no burden on competition. To the contrary, the Exchange believes that the proposed rule change would promote competition by widening the scope of executions that would be subject to lower fees and eligible for credits and providing additional clarity to the Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)(ii) of the Act[15] and subparagraph(f)(2) of Rule 19b-4 thereunder[16] because it establishes or changes a due, fee or other charge imposed by the Exchange.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File No. SR–CHX–2014–19 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File No. SR–CHX–2014–19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the CHX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CHX–2014–19 and should be submitted on or before January 7, 2015.

[11] Aside from the Institutional Broker credits under Section F.2, Section F.4 does not apply to any other credits, fee caps or rebates offered by the Exchange.

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(1).

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29493 Filed 12–16–14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73812; File No. SR–BYX–2014–037

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of BATS Y-Exchange, Inc.

December 11, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2014, BATS Y-Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members [5] and non-members of the Exchange pursuant to BYX Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its fee schedule effective immediately in order to adopt pricing for ROOC orders and to adopt pricing for orders that execute pursuant to Rule 11.23, titled ''Opening Process.''

ROOC

The Exchange recently filed a rule change to adopt a new routing strategy, ROOC, which provides that orders entered on the Exchange may be designated for participation in the opening, re-opening (following a halt suspension or pause), or closing process (collectively, an ''Auction'') of a primary listing market other than the Exchange if received before the opening/re-opening/closing time of such market.[6] As such, the Exchange proposes to adopt pricing related to this new routing strategy: the Exchange is proposing to charge $0.0015 per share for ROOC orders routed and executed in the listing market's opening or re-opening cross and charge $0.0010 per share for orders routed and executed in the listing market's closing process.

Opening Process

The Exchange recently filed and the Commission approved a proposed rule change to adopt Rule 11.23, establishing an opening and re-opening process on the Exchange in all securities (the ''Opening Process'').[7] The Opening Process is substantially similar to the opening processes on EDGA Exchange, Inc. (''EDGA'') and EDGX Exchange, Inc. (''EDGX''). The Exchange proposes that securities executed in the new Opening Process will be executed free of charge.[8]

The Exchange proposes to implement the amendments to its fee schedule effective immediately.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[9] Specifically, the Exchange believes that the proposed rule change is consistent with Sections 6(b)(4) of the Act and 6(b)(5) of the Act,[10] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive.

The Exchange believes that the proposed changes to the Exchange's fee schedule to add fees for the ROOC routing strategy when routed and executed in the listing market's Auction represent a reasonable and equitable allocation of fees because they are equal to or roughly equivalent to the fees that will be charged pursuant to the applicable exchange's fee schedule for participation in an Auction. The Exchange further believes that the proposed fees for ROOC are non-discriminatory because they apply uniformly to all Members and, again, because they approximate the fees at the away venue.

The Exchange also believes that its proposed pricing for the Opening Process is reasonable and equitable because the Exchange is proposing for executions in the Opening Process to be free of charge, which is the same price charged on EDGA for participation in its analogous opening process and $0.0005 [sic.] cheaper than such analogous opening process on EDGX, as noted above. The Exchange also believes that the proposal to provide free executions in the Opening Process on the Exchange is non-discriminatory because such proposed pricing would apply uniformly to all Members and, again, because other venues are providing

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] *See* Securities Exchange Act Release No. 73411 (October 23, 2014), 79 FR 64452 (October 29, 2014) (SR–BYX–2014–028).

[7] *See* Securities Exchange Act Release No. 73472 (October 30, 2014), 79 FR 65735 (November 5, 2014) (SR–BYX–2014–018).

[8] The Exchange notes that this proposed fee is $0.0010 less for executions in the opening process than on EDGX and the same as executions in the opening process on EDGA.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4) and (5).

executions without charge in their respective analogous processes.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. To the contrary, the Exchange believes that the proposed changes will allow the Exchange to compete more ably with other execution venues by providing additional competitive services at competitive prices, including the addition of Opening Process executions free of charge. Also, because the market for order execution is extremely competitive, Members may readily opt to disfavor the Exchange's routing services if they believe that alternatives offer them better value. For orders routed through ROOC, the proposed fees approximate the cost to the Exchange of executing the orders on away trading venues. As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if the deem fee structures to be unreasonable or excessive.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and paragraph (f)(2) of Rule 19b–4 thereunder.[12] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BYX–2014–037 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BYX–2014–037. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BYX–2014–037 and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29491 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73823; File No. SR–NASDAQ–2014–119]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Certain NASDAQ Options Market Professional User and Enterprise License Fees

December 11, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 28, 2014, The NASDAQ Stock Market LLC (''NASDAQ'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASDAQ proposes to amend Chapter XV, entitled ''Options Pricing,'' at Section 4 governing pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options. Specifically, the Exchange proposes to amend certain NOM professional user (''Professional User'') and enterprise license (''Enterprise License'') fees.

While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on January 1, 2015.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend certain NOM Professional User and Enterprise License fees.

Currently, the Exchange assesses recipients of the BONO options data feed a $5 monthly internal per Professional User fee, as well as a $5 monthly external per Professional User fee. The Exchange also assesses recipients of the ITTO options data feed a $10 monthly internal per Professional User fee, as well as a $10 monthly external per Professional User fee.

The Exchange proposes to establish a single monthly $40 per Professional User fee for internal use that will entitle such subscriber to access both the BONO and ITTO options data feeds combined. NASDAQ also proposes to establish a single monthly $40 per Professional User fee for external use that will entitle such subscriber to access both the BONO and ITTO options data feeds combined. The monthly Professional User fees per recipient covers the usage of both ITTO and BONO and recipients no longer will need to report their usage separately since they will no longer be assessed fees separately for each data product. For example, if a firm has one Professional Subscriber accessing both BONO and ITTO options data feeds for internal use, the firm would only report the Subscriber once and pay $40 ($1 for Non-Professional). The Exchange believes that by allowing access to multiple products for one price, it will allow for a broad dissemination of NOM data overall and a wider range of consumer choice. Moreover, this reduces the administrative burden on the firms since they no longer need to segregate the access of each system.

Additionally, the Exchange proposes to increase the existing monthly Enterprise License (Non-Display) Fee of $2,500 per firm to $10,000 per firm for access to the BONO and ITTO options data feeds combined. This pricing structure continues to offer two advantages. First, it establishes a monthly fee cap for distributors with large customer bases, effectively lowering average cost per user and marginal costs per user beyond the monthly breakpoint. Second, the Enterprise License offers administrative ease by eliminating the need for distributors to tally, track, and report to the Exchange a specific number of individual users every month. This is a voluntary option; distributors are permitted to choose between per user fee pricing and the Enterprise License.

The Exchange believes that although the above Professional User and Enterprise License fees are higher, the value of the BONO and ITTO options data feeds has increased significantly over the last three years. During this period NOM has witnessed strong growth both in terms of the number of listings, as well as trading market share. Specifically, NOM listings increased from 663 as of June 2011 to over 2,700 today while NOM's trading market share jumped more than 250% from July 2011 to July 2014 according to OCC data. Also, NOM technological enhancements in 2011 (referred to as NOM 2.0) expanded NOM functionality through the introduction of new versions of market data specifications in an uncompressed, binary format. Additionally, NOM's market data specifications now are the same as the market data specifications on both the NASDAQ OMX PHLX LLC and NASDAQ OMX BX, Inc. exchanges. The commonality among the market data specifications across these three markets provide for greatly increased efficiency to firms by allowing them to leverage the development work on one market across all of three markets.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides an equitable allocation of reasonable fees among Subscribers and recipients of NASDAQ data and is not designed to permit unfair discrimination between them. NASDAQ'S proposal to establish a single monthly $40 per Professional User fee for internal use and a separate single monthly $40 per Professional User fee for external use that will entitle such subscriber to access both the BONO and ITTO options data feeds combined reflects an equitable allocation of reasonable fees. The Commission has long recognized the fair and equitable and not unreasonably discriminatory nature of assessing different fees for Professional and Non-Professional users of the same data. NASDAQ also believes it is equitable to assess a higher fee per Professional User than to an ordinary non-professional user due to the enhanced flexibility and lower overall costs that it offers Distributors.

NASDAQ believes that the increase to the Enterprise License Fee from the existing monthly fee of $2,500 per firm to $10,000 per firm for access to the BONO and ITTO options data feeds combined is fair and equitable and not unreasonably discriminatory. Enterprise Licenses have long been accepted as an economically efficient form of volume discount for the heaviest users of market data (see Rule 7023 enterprise licenses). The value of the BONO and ITTO options data feeds has increased significantly over the last three years and NASDAQ notes that the Enterprise License Fee is entirely optional in that NASDAQ is not required to offer it and Distributors are not required to pay it. Accordingly, Distributors and users can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged.

In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public.

The Commission concluded that Regulation NMS—by deregulating the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[5]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to broker-dealers at all, it follows that the price at which such data is sold should be set by the market as well.

On July 21, 2010, President Barack Obama signed into law H.R. 4173, the Dodd- Frank Wall Street Reform and

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4) and (5).

[5] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

Consumer Protection Act of 2010 (''Dodd-Frank Act''), which amended Section 19 of the Act. Among other things, Section 916 of the Dodd-Frank Act amended paragraph (A) of Section 19(b)(3) of the Act by inserting the phrase ''on any person, whether or not the person is a member of the self-regulatory organization'' after ''due, fee or other charge imposed by the self-regulatory organization.'' As a result, all self-regulatory organization (''SRO'') rule proposals establishing or changing dues, fees, or other charges are immediately effective upon filing regardless of whether such dues, fees, or other charges are imposed on members of the SRO, non-members, or both. Section 916 further amended paragraph (C) of Section 19(b)(3) of the Act to read, in pertinent part, ''At any time within the 60-day period beginning on the date of filing of such a proposed rule change in accordance with the provisions of paragraph (1) [of Section 19(b)], the Commission summarily may temporarily suspend the change in the rules of the self-regulatory organization made thereby, if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of this title. If the Commission takes such action, the Commission shall institute proceedings under paragraph (2)(B) [of Section 19(b)] to determine whether the proposed rule should be approved or disapproved.''

The decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010) (''*NetCoalition I*''), upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for market data. ''In fact, the legislative history indicates that the Congress intended that the market system 'evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed' and that the SEC wield its regulatory power 'in those situations where competition may not be sufficient,' such as in the creation of a 'consolidated transactional reporting system.' *NetCoalition I,* at 535 (quoting H.R. Rep. No. 94–229, at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 321, 323).

For the reasons stated above, NASDAQ believes that the allocation of the proposed fee is fair and equitable in accordance with Section 6(b)(4) of the Act, and not unreasonably discriminatory in accordance with Section 6(b)(5) of the Act. As described above, the proposed fee is based on pricing conventions and distinctions that exist in NASDAQ's current fee schedule. These distinctions are each based on principles of fairness and equity that have helped for many years to maintain fair, equitable, and not unreasonably discriminatory fees, and that apply with equal or greater force to the current proposal.

As described in greater detail below, if NASDAQ has calculated improperly and the market deems the proposed fees to be unfair, inequitable, or unreasonably discriminatory, firms can discontinue the use of their data because the proposed product is entirely optional to all parties. Firms are not required to purchase data and NASDAQ is not required to make data available or to offer specific pricing alternatives for potential purchases. NASDAQ can discontinue offering a pricing alternative (as it has in the past) and firms can discontinue their use at any time and for any reason (as they often do), including due to their assessment of the reasonableness of fees charged. NASDAQ continues to establish and revise pricing policies aimed at increasing fairness and equitable allocation of fees among Subscribers.

NASDAQ believes that periodically it must adjust fees to reflect market forces and NASDAQ believes it is an appropriate time to adjust this fee. This also reflects that the market for this Depth-of-Book information is highly competitive and continually evolves as products develop and change.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Notwithstanding its determination that the Commission may rely upon competition to establish fair and equitably allocated fees for market data, the *NetCoalition* court found that the Commission had not, in that case, compiled a record that adequately supported its conclusion that the market for the data at issue in the case was competitive. NASDAQ believes that a record may readily be established to demonstrate the competitive nature of the market in question.

There is intense competition between trading platforms that provide transaction execution and routing services and proprietary data products. Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. Data products are valuable to many end Subscribers only insofar as they provide information that end Subscribers expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, an exchange's customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A broker-dealer will direct orders to a particular exchange only if the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the broker-dealer chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the broker-dealer will choose not to buy it. Moreover, as a broker-dealer chooses to direct fewer orders to a particular exchange, the value of the product to that broker-dealer decreases, for two reasons. First, the product will contain less information, because executions of the broker-dealer's orders will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that broker-dealer because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the broker-dealer is directing orders will become correspondingly more valuable.

Thus, an increase in the fees charged for either transactions or data has the potential to impair revenues from both products. ''No one disputes that competition for order flow is 'fierce'.'' *NetCoalition* at 24. However, the existence of fierce competition for order flow implies a high degree of price sensitivity on the part of broker-dealers with order flow, since they may readily reduce costs by directing orders toward the lowest-cost trading venues. A broker-dealer that shifted its order flow from one platform to another in response to order execution price differentials would both reduce the value of that platform's market data and reduce its own need to consume data

from the disfavored platform. Similarly, if a platform increases its market data fees, the change will affect the overall cost of doing business with the platform, and affected broker-dealers will assess whether they can lower their trading costs by directing orders elsewhere and thereby lessening the need for the more expensive data.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus, because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among trading platforms can be expected to constrain the aggregate return each platform earns from the sale of its joint products, but different platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some platforms may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market information, and setting relatively low prices for accessing posted liquidity. In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering. This would be akin to strictly regulating the price that an automobile manufacturer can charge for car sound systems despite the existence of a highly competitive market for cars and the availability of after-market alternatives to the manufacturer-supplied system.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market.

Broker-dealers currently have numerous alternative venues for their order flow, including thirteen SRO markets, as well as internalizing broker-dealers (''BDs'') and various forms of alternative trading systems (''ATSs''), including dark pools and electronic communication networks (''ECNs''). Each SRO market competes to produce transaction reports via trade executions, and two FINRA-regulated Trade Reporting Facilities (''TRFs'') compete to attract internalized transaction reports. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products.

The large number of SROs, TRFs, BDs, and ATSs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including NASDAQ, New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC, NYSE Arca LLC, and BATS Exchange, Inc. (''BATS'').

Any ATS or BD can combine with any other ATS, BD, or multiple ATSs or BDs to produce joint proprietary data products. Additionally, order routers and market data vendors can facilitate single or multiple broker-dealers' production of proprietary data products. The potential sources of proprietary products are virtually limitless.

The fact that proprietary data from ATSs, BDs, and vendors can by-pass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products, as BATS and Arca did before registering as exchanges by publishing data on the Internet. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the data available in proprietary products is exponentially greater than the actual number of orders and transaction reports that exist in the marketplace.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end Subscribers. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Thomson Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end Subscribers will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: They can simply refuse to purchase any proprietary data product that fails to provide sufficient value. NASDAQ and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN and BATS Trading. A proliferation of dark pools and other ATSs operate profitably with fragmentary shares of consolidated market volume.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While broker-dealers have previously published their proprietary data individually, Regulation NMS encourages market data vendors and broker-dealers to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, and Thomson Reuters.

The vigor of competition for information is significant. NASDAQ has made a determination to adjust the fees associated with these products in order to reflect more accurately the value of its products and the investments made to enhance them, as well as to keep pace with changes in the industry and evolving customer needs. These products are entirely optional and are geared towards attracting new

customers, as well as retaining existing customers.

The Exchange has witnessed competitors creating new products and innovative pricing in this space over the course of the past year. NASDAQ continues to see firms challenge its pricing on the basis of the Exchange's explicit fees being higher than the zero-priced fees from other competitors such as BATS. In all cases, firms make decisions on how much and what types of data to consume on the basis of the total cost of interacting with NASDAQ or other exchanges. Of course, the explicit data fees are but one factor in a total platform analysis. Some competitors have lower transactions fees and higher data fees, and others are vice versa. For example, NOM offers one distributor fee which allows firms to access both the BONO and ITTO data feeds. The market for this information is highly competitive and continually evolves as products develop and change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[6] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2014–119 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2014–119. 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 Website viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2014–119, and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29499 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(a)[sic](ii).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73831; File No. SR–BOX–2014–27]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Interpretive Material to Rule 7150 (Price Improvement Period ''PIP'') and Interpretive Material to Rule 7245 (Complex Order Price Improvement Period ''COPIP'') To Extend the Pilot Period That Permit the Exchange To Have No Minimum Size Requirement for Orders Entered Into the PIP and COPIP Until July 18, 2015

December 12, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 5, 2014, BOX Options Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Interpretive Material to Rule 7150 (Price Improvement Period ''PIP'') and Interpretive Material to Rule 7245 (Complex Order Price Improvement Period ''COPIP'') to extend the pilot programs that permit the Exchange to have no minimum size requirement for orders entered into the PIP (''PIP Pilot Program'') and COPIP (''COPIP Pilot Program''). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to extend the PIP and COPIP Pilot Programs for an additional seven months or until the date on which the pilot programs are approved on a permanent basis, whichever is earlier. The PIP and COPIP Pilot Programs allow the Exchange to have no minimum size requirement for orders entered into the PIP [3] and the COPIP.[4] The Exchange has committed to provide certain data to the Commission during the PIP and COPIP Pilot Programs.[5] The proposed rule change retains the text of IM–7150–1 to Rule 7150 and IM–7245–1 to Rule 7245; and seeks to extend the operation of the PIP and COPIP Pilot Programs until July 18, 2015.

The Exchange notes that the PIP and COPIP Pilot Programs permit Participants to trade with their customer orders that are less than 50 contracts. In particular, any order entered into the PIP is guaranteed an execution at the end of the auction at a price at least equal to the national best bid or offer. Any order entered into the COPIP is guaranteed an execution at the end of the auction at a price at least equal to or better than the cNBBO,[6] cBBO [7] and BBO on the Complex Order Book for the Strategy at the time of commencement. In further support of this proposed rule change, the Exchange will submit to the Commission monthly a PIP Pilot Program Report and a COPIP Pilot Program Report, offering detailed data from, and analysis of, the PIP Pilot Program and COPIP Pilot Program.

The Exchange believes that, by extending the expiration of the PIP and COPIP Pilot Programs, the proposed rule change will allow for further analysis of the PIP and COPIP Pilot Programs and a determination of how the PIP and COPIP Pilot Programs shall be structured in the future.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[8] in general, and Section 6(b)(5) of the Act,[9] in particular, in that it is designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the data demonstrates that there is sufficient investor interest and demand to extend the PIP and COPIP Pilot Programs for an additional seven months or until the date on which the pilot programs are approved on a permanent basis, whichever is earlier. The Exchange represents that the PIP and COPIP Pilot Programs are designed to create tighter markets and ensure that each order receives the best possible price.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the PIP and COPIP Pilot Programs, the proposed rule change will allow for further analysis of the PIP and COPIP Pilot Programs and a determination of how the PIP and COPIP Pilot Programs shall be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) [11] thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.[12]

A proposed rule change filed under Rule 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing. However, Rule 19b–

[3] The PIP Pilot Program is currently set to expire on December 18, 2014. *See* Securities Exchange Act Release Nos. 66871 (April 27, 2012) 77 FR 26323 (May 3, 2012) (File No.10–206, In the Matter of the Application of BOX Options Exchange LLC for Registration as a National Securities Exchange Findings, Opinion, and Order of the Commission), 67255 (June 26, 2012) 77 FR 39315 (July 2, 2013) (SR–BOX–2012–009) (Notice of Filing and Immediate Effectiveness of a Proposal To Extend a Pilot Program That Permits BOX to Have No Minimum Size Requirement for Orders Entered Into the Price Improvement Period), 69846 (June 25, 2013) 78 FR 39365 (July 1, 2013) (SR–BOX–2013–33) (Notice of Filing and Immediate Effectiveness of a Proposal To Extend a Pilot Program That Permits BOX to Have No Minimum Size Requirement for Orders Entered Into the Price Improvement Period), 72545 (July 7, 2014) 79 FR 40182 (July 11, 2014) (SR–BOX–2014–19) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to amend Interpretive Material to Rule 7150 (Price Improvement Period ''PIP'') and Interpretive Material to Rule 7245 (Complex Order Price Improvement Period ''COPIP''), and 73314 (October 7, 2014) 79 FR 61682 (October 14, 2014) (SR–BOX–2014–23) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Pilot Programs That Permit the Exchange To Have No Minimum Size Requirement for Orders Entered Into the PIP (''PIP Pilot Program'') and COPIP (''COPIP Pilot Program'') Until December 18, 2014).

[4] The COPIP Pilot Program is currently set to expire on December 18, 2014. *See* Securities Exchange Act Release Nos. 71148 (December 19, 2013) 78 FR 78437 (December 26, 2013) (Notice of Filing of Amendment Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, to Permit Complex Orders to Participate in Price Improvement Periods), 72545 (July 7, 2014) 79 FR 40182 (July 11, 2014) (SR–BOX–2014–19) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to amend Interpretive Material to Rule 7150 (Price Improvement Period ''PIP'') and Interpretive Material to Rule 7245 (Complex Order Price Improvement Period ''COPIP''), and 73314 (October 7, 2014) 79 FR 61682 (October 14, 2014) (SR–BOX–2014–23) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Pilot Programs That Permit the Exchange To Have No Minimum Size Requirement for Orders Entered Into the PIP (''PIP Pilot Program'') and COPIP (''COPIP Pilot Program'') Until December 18, 2014).

[5] *See* supra note 3 at 26334 and note 4 at 78441.

[6] As defined in BOX Rule 7240(a)(3), the term ''cNBBO'' means the best net bid and offer price for a Complex Order Strategy based on the NBBO for the individual options components of such Strategy.

[7] As defined in BOX Rule 7240(a)(1), the term ''cBBO'' means the best net bid and offer price for a Complex Order Strategy based on the BBO on the BOX Book for the individual options components of such Strategy.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

4(f)(6)(iii) [13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay period so the pilot programs can continue without interruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the pilot programs to continue uninterrupted, thereby avoiding any potential investor confusion that could result from a temporary interruption in the pilot programs. For these reasons, the Commission designates the proposed rule change to be operative on December 18, 2014.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[15]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2014–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2014–27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2014–27 and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29621 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78s(b)(3)(C).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73818; File No. SR–NYSEArca–2014–110]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Amending Rule 6.2A To Authorize the Exchange to Share Any User-Designated Risk Settings in Exchange Systems With the Clearing Member That Clears Transactions on Behalf of the User

December 11, 2014.

I. Introduction

On September 19, 2014, NYSE Arca, Inc., (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 6.2A to authorize the Exchange to share any User-designated risk settings in Exchange systems with the Clearing Member [3] that clears transactions on behalf of the User.[4] The proposed rule change was published for comment in the **Federal Register** on October 7, 2014.[5] On November 19, 2014, the Exchange submitted Amendment No. 1 to the proposed rule change.[6] On November 21, 2014, pursuant to Section 19(b)(2) of the Exchange Act,[7] 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.[8] The Commission received no comments on the proposal. The Commission is publishing this notice to solicit comments from interested persons on Amendment No. 1 to the proposed rule change and is approving the proposed rule change, as modified by Amendment No. 1 thereto, on an accelerated basis.

II. Description of the Proposal

The Exchange proposes to amend Exchange Rule 6.2A (Access to and Conduct on OX) to state that the Exchange may share any User-designated risk settings in the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 6.1(b)(3) defining ''Clearing Member'' as ''an Exchange OTP Firm or OTP Holder which has been admitted to membership in the Options Clearing Corporation pursuant to the provisions of the Rules of the Options Clearing Corporation.''

[4] *See* Exchange Rule 6.1A(a)(19) defining ''User'' as ''any OTP Holder, OTP Firm or Sponsored Participant that is authorized to obtain access to OX pursuant to Rule 6.2A.''

[5] *See* Securities Exchange Act Release No. 73281 (October 1, 2014), 79 FR 60552 (''Notice'').

[6] In Amendment No. 1, the Exchange provided additional justification for why the Exchange believes the proposed rule change is consistent with the Act. In Amendment No. 1, the Exchange states, among other things, that the Exchange believes that sharing a User's risk settings directly with its Clearing Member could reduce the administrative burden on Users to provide that information to their Clearing Members themselves and notes that any User could become a Clearing Member, which would allow the User to avoid sharing its risk settings with any third party. Amendment No. 1 has been placed in the public comment file for SR–NYSEArca–2014–110 at *http://www.sec.gov/comments/sr-nysearca-2014-110/nysearca2014110-1.pdf* (*See* letter to Kevin M. O'Neill, Deputy Secretary, Commission, from Martha Redding, Chief Counsel and Assistant Corporate Secretary, New York Stock Exchange, dated November 20, 2014) and is also available on the Exchange's Web site.

[7] 15 U.S.C. 78s(b)(2).

[8] *See* Securities Exchange Act Release No. 34–73668, 79 FR 70607 (November 26, 2014). The Commission designated January 5, 2014 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

Exchange's OX [9] system with the Clearing Member that clears transactions on behalf of the User.[10]

The Exchange states that while not all Users are Clearing Members, all Users require a Clearing Member's consent to clear transactions on their behalf in order to conduct business on the Exchange.[11] The Exchange states that each User that transacts through a Clearing Member on the Exchange executes a Clearing Letter of Consent, which codifies the relationship between each User and Clearing Member and provides the Exchange with notice of which Clearing Members have relationships with which Users.[12] The Exchange states that the Clearing Member that guarantees the User's transactions on the Exchange has a financial interest in understanding the risk tolerance of the User, and that the proposal would provide the Exchange with authority to directly provide Clearing Members with information that may otherwise be available to such Clearing Members by virtue of their relationship with the respective Users.[13]

The Exchange states that the User-designated risk settings that the Exchange may share with a User's Clearing Member under the proposal are set forth in Exchange Rule 6.40 (Risk Limitation Mechanism).[14] The Exchange states that it may adopt additional rules providing for User-enabled risk settings other than those provided in Exchange Rule 6.40 that could be shared with a User's Clearing Member under the proposal, and the Exchange would announce these additional risk settings via Trader Update.[15]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and Section 6(b)(8) of the Act,[18] which requires that the rules of the exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposed rule change will allow the Exchange to directly provide a User's designated risk settings to the Clearing Member that clears trades on behalf of the User. The Exchange states that because a Clearing Member that executes a Clearing Letter of Consent on behalf of a User guarantees all transactions of that User, and therefore bears the risk associated with those transactions, it is appropriate for the Clearing Member to have knowledge of what risk settings the User may utilize within the Exchange's systems.[19] The Exchange states that the proposal will permit Clearing Members, who have a financial interest in the risk settings of Users with whom the Clearing Member has entered into a Clearing Letter of Consent, to better monitor and manage the potential risks assumed by Users, thereby providing Clearing Members with greater control and flexibility over setting their own risk tolerance and exposure and aiding Clearing Members in complying with the Act.[20] The Exchange further states that, to the extent a Clearing Member might reasonably require a User to provide access to its risk settings as a prerequisite to continuing to clear trades on the User's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Users and ensures that Clearing Members are receiving information that is up-to-date and conforms to the settings active in Exchange systems.[21]

The Exchange also states that it does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.[22] According to the Exchange, the proposed rule change is not designed to address any competitive issues and does not pose an undue burden on non-Clearing Members because, unlike Clearing Members, non-Clearing Members do not guarantee the execution of the User transactions on the Exchange.[23] The Exchange notes further that the proposal is structured to offer the same enhancement to all Clearing Members, regardless of size, and would not impose a competitive burden on any participant.[24] In addition, the Exchange states that any User that does not wish to share its designated risk settings with its Clearing Member could avoid sharing such settings by becoming a clearing member of the Options Clearing Corporation.[25]

Accordingly, the Commission finds that the proposal to allow the Exchange to directly provide a User's designated risk settings to the Clearing Member that clears trades on behalf of the User, guarantees all transactions of that User, and therefore bears the risk associated with those transactions, is consistent with the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2014–110 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–2014–110. This file number should be included on the subject line if email is used. To help the Commission process and review your

[9] *See* Exchange Rule 6.1A(a)(13) defining ''OX'' as ''the Exchange's electronic order delivery, execution and reporting system for designated option issues through which orders and quotes of Users are consolidated for execution and/or display. . . .''

[10] *See* proposed Exchange Rule 6.2A.

[11] *See* Amendment No. 1.

[12] *See* Notice, *supra* note 5, at 60552. *See also* NYSE Arca Options OTP Application, Section 8 (Clearing Letter of Consent), available at: *https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_OTP_Firm_Application.pdf.*

[13] *See* Notice, *supra* note 5, at 60552.

[14] *Id.* According to the Exchange, pursuant to Rule 6.40(b)–(d), Users may set certain risk control thresholds in the Risk Limitation Mechanism, which are designed to mitigate the potential risks of multiple executions against a User's trading interest. *Id.*

[15] *See id.* at n.9.

[16] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78f(b)(8).

[19] *See* Notice, *supra* note 5, at 60552.

[20] *Id.* at 60553. *See also* Amendment No. 1.

[21] *See* Amendment No. 1.

[22] *See* Notice, *supra* note 5, at 60553.

[23] *Id.*

[24] *Id.*

[25] *See* Amendment No. 1.

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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2014–110, and should be submitted on or before January 7, 2015.

V. Accelerated Approval of Proposed Rule Change, As Modified by Amendment No. 1

As discussed above, the Exchange submitted Amendment No. 1 to provide further justification as to why the Exchange believes the proposed rule change is consistent with the Act. The Exchange states in Amendment No. 1, among other things, that to the extent a Clearing Member might reasonably require a User to provide access to its risk settings as a prerequisite to continuing to clear trades on the User's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Users and ensures that Clearing Members are receiving information that is up-to-date and conforms to the settings active in Exchange systems. The Exchange further notes in Amendment No. 1 that any User may become a Clearing Member, which would enable that User to avoid sharing risk settings with any third party. The Commission believes that Amendment No. 1 does not materially affect the substance of the proposed rule change or raise any novel or unique regulatory issues. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[26] for approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[27] that the proposed rule change (SR–NYSEArca–2014–110), as modified by Amendment No. 1 thereto, be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29496 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[26] 15 U.S.C. 78s(b)(2).

[27] *Id.*

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73817; File No. SR–NYSEMKT–2014–81]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Amending Rule 902.1NY To Authorize the Exchange To Share Any User-Designated Risk Settings in Exchange Systems with the Clearing Member that Clears Transactions on Behalf of the User

December 11, 2014.

I. Introduction

On September 19, 2014, NYSE MKT LLC, (''NYSE MKT'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 902.1NY to authorize the Exchange to share any User-designated risk settings in Exchange systems with the Clearing Member [3] that clears transactions on behalf of the User.[4] The proposed rule change was published for comment in the **Federal Register** on October 7, 2014.[5] On November 19, 2014, the Exchange submitted Amendment No. 1 to the proposed rule change.[6] On November 21, 2014, pursuant to Section 19(b)(2) of the Exchange Act,[7] 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.[8] The Commission received one comment on the proposal.[9] The Commission is publishing this notice to solicit comments from interested persons on Amendment No. 1 to the proposed rule change and is approving the proposed rule change, as modified by Amendment No. 1 thereto, on an accelerated basis.

II. Description of the Proposal

The Exchange proposes to amend Exchange Rule 902.1NY (Admission to the System) to state that the Exchange may share any User-designated risk settings in the Exchange's System [10] with the Clearing Member that clears transactions on behalf of the User.[11]

The Exchange states that while not all Users are Clearing Members, all Users require a Clearing Member's consent to clear transactions on their behalf in order to conduct business on the Exchange.[12] The Exchange states that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 900.2NY (11) defining ''Clearing Member'' as ''an Exchange ATP Holder which has been admitted to membership in the Options Clearing Corporation pursuant to the provisions of the Rules of the Options Clearing Corporation.''

[4] *See* Exchange Rule 900.2NY (87) defining ''User'' as ''any ATP Holder that is authorized to obtain access to the System pursuant to Rule 902.1NY.''

[5] *See* Securities Exchange Act Release No. 73280 (October 1, 2014), 79 FR 60553 (''Notice'').

[6] In Amendment No. 1, the Exchange provided additional justification for why the Exchange believes the proposed rule change is consistent with the Act. In Amendment No. 1, the Exchange states, among other things, that the Exchange believes that sharing a User's risk settings directly with its Clearing Member could reduce the administrative burden on Users to provide that information to their Clearing Members themselves and notes that any User could become a Clearing Member, which would allow the User to avoid sharing its risk settings with any third party. Amendment No. 1 has been placed in the public comment file for SR–NYSEMKT–2014–81 at *http://www.sec.gov/comments/sr-nysemkt-2014-81/nysemkt201481-2.pdf* (*See* letter to Kevin M. O'Neill, Deputy Secretary, Commission, from Martha Redding, Chief Counsel and Assistant Corporate Secretary, New York Stock Exchange, dated November 20, 2014) and is also available on the Exchange's Web site.

[7] 15 U.S.C. 78s(b)(2).

[8] *See* Securities Exchange Act Release No. 34–73669, 79 FR 70903 (November 28, 2014). The Commission designated January 5, 2014 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[9] *See* Letter from Dr. Lee Jackson, Esq., dated October 1, 2014. This commenter's letter was incoherent and irrelevant to the proposed rule change.

[10] According to the Exchange, ''System'' refers to the Exchange System facility. *See* Notice, *supra* note 5, at 60554. *See also* Exchange Rule 900.1NY.

[11] *See* proposed Exchange Rule 902.1NY.

[12] *See* Amendment No. 1.

each User that transacts through a Clearing Member on the Exchange executes a Clearing Letter of Consent, which codifies the relationship between each User and Clearing Member and provides the Exchange with notice of which Clearing Members have relationships with which Users.[13] The Exchange states that the Clearing Member that guarantees the User's transactions on the Exchange has a financial interest in understanding the risk tolerance of the User, and that the proposal would provide the Exchange with authority to directly provide Clearing Members with information that may otherwise be available to such Clearing Members by virtue of their relationship with the respective Users.[14]

The Exchange states that the User-designated risk settings that the Exchange may share with a User's Clearing Member under the proposal are set forth in Exchange Rule 928NY (Risk Limitation Mechanism).[15] The Exchange states that it may adopt additional rules providing for User-enabled risk settings other than those provided in Exchange Rule 928NY that could be shared with a User's Clearing Member under the proposal, and the Exchange would announce these additional risk settings via Trader Update.[16]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[17] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[18] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and Section 6(b)(8) of the Act,[19] which requires that the rules of the exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposed rule change will allow the Exchange to directly provide a User's designated risk settings to the Clearing Member that clears trades on behalf of the User. The Exchange states that because a Clearing Member that executes a Clearing Letter of Consent on behalf of a User guarantees all transactions of that User, and therefore bears the risk associated with those transactions, it is appropriate for the Clearing Member to have knowledge of what risk settings the User may utilize within the Exchange's systems.[20] The Exchange states that the proposal will permit Clearing Members, who have a financial interest in the risk settings of Users with whom the Clearing Member has entered into a Clearing Letter of Consent, to better monitor and manage the potential risks assumed by Users, thereby providing Clearing Members with greater control and flexibility over setting their own risk tolerance and exposure and aiding Clearing Members in complying with the Act.[21] The Exchange further states that, to the extent a Clearing Member might reasonably require a User to provide access to its risk settings as a prerequisite to continuing to clear trades on the User's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Users and ensures that Clearing Members are receiving information that is up-to-date and conforms to the settings active in Exchange systems.[22]

The Exchange also states that it does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.[23] According to the Exchange, the proposed rule change is not designed to address any competitive issues and does not pose an undue burden on non-Clearing Members because, unlike Clearing Members, non-Clearing Members do not guarantee the execution of the User transactions on the Exchange.[24] The Exchange notes further that the proposal is structured to offer the same enhancement to all Clearing Members, regardless of size, and would not impose a competitive burden on any participant.[25] In addition, the Exchange states that any User that does not wish to share its designated risk settings with its Clearing Member could avoid sharing such settings by becoming a clearing member of the Options Clearing Corporation.[26]

Accordingly, the Commission finds that the proposal to allow the Exchange to directly provide a User's designated risk settings to the Clearing Member that clears trades on behalf of the User, guarantees all transactions of that User, and therefore bears the risk associated with those transactions, is consistent with the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2014–81 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2014–81. 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

[13] *See* Notice, *supra* note 5, at 60554. *See also* NYSE Amex Options ATP Application, Section 8 (Clearing Letter of Consent), available at: *https://www.nyse.com/publicdocs/nyse/markets/amex-options/ATP_Application.pdf.*.

[14] *See* Notice, *supra* note 5, at 60554.

[15] *Id.* According to the Exchange, pursuant to Rule 928NY(b)–(d), Users may set certain risk control thresholds in the Risk Limitation Mechanism, which are designed to mitigate the potential risks of multiple executions against a User's trading interest. *Id.*

[16] *See id.* at n.9.

[17] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b)(8).

[20] *See* Notice, *supra* note 5, at 60554.

[21] *Id. See also* Amendment No. 1.

[22] *See* Amendment No. 1.

[23] *See* Notice, *supra* note 5, at 60554.

[24] *Id.*

[25] *Id.*

[26] *See* Amendment No. 1.

Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2014–81, and should be submitted on or before January 7, 2015.

V. Accelerated Approval of Proposed Rule Change, As Modified by Amendment No. 1

As discussed above, the Exchange submitted Amendment No. 1 to provide further justification as to why the Exchange believes the proposed rule change is consistent with the Act. The Exchange states in Amendment No. 1, among other things, that to the extent a Clearing Member might reasonably require a User to provide access to its risk settings as a prerequisite to continuing to clear trades on the User's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on Users and ensures that Clearing Members are receiving information that is up-to-date and conforms to the settings active in Exchange systems. The Exchange further notes in Amendment No. 1 that any User may become a Clearing Member, which would enable that User to avoid sharing risk settings with any third party. The Commission believes that Amendment No. 1 does not materially affect the substance of the proposed rule change or raise any novel or unique regulatory issues. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[27] for approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[28] that the proposed rule change (SR–NYSEMKT–2014–81), as modified by Amendment No. 1 thereto, be and it hereby is, approved on an accelerated basis.

[27] 15 U.S.C. 78s(b)(2).

[28] *Id.*

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29495 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73821; File No. SR–NYSE–2014–65]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Amending Its Continued Listing Requirements in Relation to the Late Filing of a Company's Annual Report With the Securities and Exchange Commission as set Forth in Section 802.01E of the Exchange's Listed Company Manual

December 11, 2014.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 4, 2014, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its continued listing requirements in relation to the late filing of a company's annual report with the Securities and Exchange Commission (''SEC'' or ''Commission'') as set forth in Section 802.01E of the Exchange's Listed Company Manual (the ''Manual''). The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its continued listing requirements in relation to the late filing of a company's annual report with the SEC as set forth in Section 802.01E (the ''Late Filer Rule'') of the Manual. As amended, the Late Filer Rule will (i) expand the rule to impose a maximum period within which a company must file a late quarterly report on Form 10–Q in order to maintain its listing and (ii) clarify the Exchange's treatment of companies whose annual or quarterly reports are defective at the time of filing or become defective at some subsequent date.

In its current form, the Late Filer Rule deems a listed company to be delinquent in filing its annual report on Forms 10–K, 20–F, 40–F or N–CSR with the SEC if it fails to submit the filing by the date such report was required to be filed by the applicable form, or if a Form 12b–25 was timely filed with the SEC, the extended filing due date for the annual report. During the six-month period from the date of such delinquency, the Exchange monitors the company and the status of the delinquent annual report, including through contact with the company, until the filing delinquency is cured. If the company fails to cure such delinquency within the initial six-month period, the Exchange may, in its sole discretion, allow the company's securities to be traded for up to an additional six-month period depending on the company's specific circumstances. If the Exchange determines that an additional trading period of up to six months is not appropriate, suspension and delisting procedures are commenced in accordance with the procedures set out in Section 804.00 of the Listed Company Manual.

A company is not currently subject to the compliance periods set forth in the Late Filer Rule in connection with a failure to timely file a quarterly report

[29] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

on Form 10–Q with the SEC.[4] The Exchange now proposes to extend the application of the rule to the late filing of Form 10–Qs. As proposed, a company would be deemed to be a delinquent filer under the amended rule as of the due date (or extended due date if a Form 12b–25 is timely filed with the SEC) (the ''Filing Due Date'') of the first 10–Q or annual report with respect to which a company incurs a delinquency (a ''Late Filing Delinquency'').[5] The Exchange will also deem a company to have incurred a Late Filing Delinquency if it submits an annual report or Form 10–Q to the SEC by the applicable Filing Due Date, but such filing is deficient in some respect in meeting the requirements of the applicable SEC form and the Exchange determines in its sole discretion that such deficiency is material in nature.[6]

In addition, the Exchange proposes to clarify its treatment of a company:

- That files its annual report without an audit report from its independent auditor for any or all of the periods included in such annual report (a ''Required Audit Report'' and the absence of a Required Audit Report, a ''Required Audit Report Delinquency'');
- whose independent auditor withdraws a Required Audit Report or the company files a Form 8–K with the SEC pursuant to Item 4.02(b) thereof disclosing that it has been notified by its independent auditor that a Required Audit Report or completed interim review should no longer be relied upon (a ''Required Audit Report Withdrawal Delinquency''); or
- that files a Form 8–K with the SEC pursuant to Item 4.02(a) thereof to disclose that previously issued financial statements should no longer be relied upon because of an error in such financial statements or, in the case of a foreign private issuer, makes a similar disclosure in a Form 6–K filed with the SEC or by other means (a ''Non-Reliance Disclosure'') and, in either case, the company does not refile all required corrected financial statements within 60 days of the issuance of the Non-Reliance Disclosure (an ''Extended Non-Reliance Disclosure Event'' and, together with a Late Filing Delinquency, a Required Audit Report Delinquency and a Required Audit Report Withdrawal Delinquency, a ''Filing Delinquency'').[7]

Upon the occurrence of a Filing Delinquency, the Exchange will promptly (typically within five business days) send written notification to a company of its procedures relating to late filings. During the six-month period from the date of the Filing Delinquency (the ''Initial Cure Period''), the Exchange will monitor the company and the status of the Delinquent Report and any subsequent annual report or quarterly report on Form 10–Q the company fails to file by the applicable Filing Due Date (a ''Subsequent Report''), through contact with the company, until the Filing Delinquency is cured.[8] If the company fails to cure the Filing Delinquency within the Initial Cure Period, the Exchange may, in its sole discretion, allow the company's securities to be traded for up to an additional six-month period (the ''Additional Cure Period'') depending on the company's specific circumstances. If the Exchange determines that an Additional Cure Period is not appropriate, suspension and delisting procedures will commence in accordance with the procedures set out in Section 804.00 of the Listed Company Manual. A company is not eligible to follow the procedures outlined in Sections 802.02 and 802.03 with respect to this criterion. Notwithstanding the foregoing, however, the Exchange may in its sole discretion decide (i) not to afford a company any Initial Cure Period or Additional Cure Period, as the case may be, at all or (ii) at any time during the Initial Cure Period or Additional Cure Period, as the case may be, to truncate the Initial Cure Period or Additional Cure Period, as the case may be, and immediately commence suspension and delisting procedures if the company is subject to delisting pursuant to any other provision of the Listed Company Manual, including if the Exchange believes, in its sole discretion, that continued listing and trading of a company's securities on the Exchange is inadvisable or unwarranted in accordance with Sections 802.01A, 802.01B, 802.01C or 802.01D of the Listed Company Manual. The Exchange may also commence suspension and delisting procedures if it believes, in its sole discretion, that it is advisable to do so on the basis of an analysis of all relevant factors, including, but not limited to, the following:

- Whether there are allegations of financial fraud or other illegality in relation to the company's financial reporting;
- the resignation or termination by the company of the company's independent auditor due to a disagreement;
- any extended delay in appointing a new independent auditor after a prior auditor's resignation or termination;
- the resignation of members of the company's audit committee or other directors;
- the resignation or termination of the company's chief executive officer, chief financial officer or other key senior executives;
- any evidence that it may be impossible for the company to cure its Filing Delinquency within the cure periods otherwise available under the Late Filer Rule; and
- any past history of late filings.

In determining whether an Additional Cure Period after the expiration of the Initial Cure Period is appropriate, the

[4] While a company is not currently subject to the compliance periods in the Late Filer Rule in connection with the failure to timely file a Form 10–Q, such companies are subject to the Exchange's late filer (or ''.LF'') indicator process. The .LF indicator is appended to the company's trading symbol as disseminated on the consolidated tape and to market data vendors and the company's name is included on the late filer list on the Exchange's Web site. The .LF indicator and web posting commence five days after the due date or extended due date (if applicable) of the first late annual report or Form 10–Q (unless the company has submitted the required report within that five day period) and continue until the company becomes current again with respect to all required periodic reports.

[5] The annual report or quarterly report on Form 10–Q that gives rise to a Late Filing Delinquency shall be referred to in the Late Filer Rule as amended as the ''Delinquent Report.''

[6] The following is a non-exclusive list of elements that, if missing from a filing, would cause the Exchange to deem the company to have incurred a Late Filing Delinquency: The filing does not include required financial statements or a required audit opinion; a required financial statement audit opinion includes qualifying or disclaiming language or the auditor provides an adverse financial statement audit opinion; a required financial statement audit opinion is unsigned or undated; there is a discrepancy between the period end date for required financial statements and the date cited in the related audit report; the company's auditor has not conducted a SAS 100 review with respect to the company's Form 10–Q; required chief executive officer or chief financial officer certifications are missing; missing Sarbanes-Oxley Act Section 404 required internal control report or auditor certification; the filing does not comply with the applicable SEC XBRL requirements; or the filing does not include signatures of officers or directors required by the applicable form. In making this determination, the Exchange is simply applying its own rules and is not making any judgment as to the sufficiency of the filing in question for purposes of compliance with any requirement under SEC rules.

[7] For purposes of the cure periods described herein, an Extended Non-Reliance Disclosure Event will be deemed to have occurred on the date of original issuance of the Non-Reliance Disclosure. If the Exchange believes that a company is unlikely to refile all required corrected financial statements within 60 days after a Non-Reliance Disclosure or that the errors giving rise to such Non-Reliance Disclosure are particularly severe in nature, the Exchange may, in its sole discretion, determine earlier than 60 days that the applicable company has incurred a Filing Delinquency as a result of such Non-Reliance Disclosure.

[8] Under the Late Filer Rule as amended, a company that has an uncured Filing Delinquency will not incur an additional Filing Delinquency if it fails to file a Subsequent Report by the applicable Filing Due Date. However, in order to cure its initial Filing Delinquency, no Subsequent Report may be delinquent or deficient on the date by which the initial Filing Delinquency is required to be cured.

Exchange will consider the likelihood that the Delinquent Report and all Subsequent Reports can be filed or refiled, as applicable, during the Additional Cure Period, as well as the company's general financial status, based on information provided by a variety of sources, including the company, its audit committee, its outside auditors, the staff of the SEC and any other regulatory body. The Exchange strongly encourages companies to provide ongoing disclosure on the status of the Delinquent Report and any Subsequent Reports to the market through press releases, and will also take the frequency and detail of such information into account in determining whether an additional trading period is appropriate.

If the Exchange determines that an Additional Cure Period is appropriate and the company fails to file the Delinquent Report and all Subsequent Reports by the end of such additional period, suspension and delisting procedures will commence immediately in accordance with the procedures set out in Section 804.00. In no event will the Exchange continue to trade a company's securities if (i) it has failed to cure its Filing Delinquency and (ii) is not current with all Subsequent Reports, on the date that is twelve months after its initial Filing Delinquency.

The Exchange proposes that the revised Late Filer Rule will become operative on March 1, 2015. Accordingly, the current provisions of Section 802.01E of the Manual will be applicable to any listed company that fails to timely file an annual report (Forms 10–K, 20–F, 40–F or N–CSR) prior to March 1, 2015. On or after March 1, 2015, any listed company that fails to timely file an annual report (Forms 10–K, 20–F, 40–F or N–CSR) or quarterly report on Form 10–Q will be subject to the amended provisions of Section 802.01E. Any listed company that is late as of March 1, 2015, in filing a Form 10–Q with a due date prior to that date will not be subject to the proposed amended rule with respect to that filing. However, any such company will be subject to the proposed amended rule with respect to any periodic report it does not file on a timely basis whose due date is on or after March 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that the proposed amendment is consistent with the investor protection objectives of Section 6(b)(5) because: (i) It strengthens the Exchange's continued listing requirements with respect to delinquent SEC filings by deeming companies delinquent if they fail to file their annual report or Form 10–Q on a timely basis and by subjecting companies to the late filer process if there are material inadequacies in their required annual or quarterly filings; and (ii) the more stringent requirements will encourage listed companies to submit timely and compliant periodic reports to the SEC.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The proposed rule change does not affect competition in any way, but rather simply seeks to protect investors by insuring that companies cannot remain listed for any extended period of time without appropriately filing their required periodic financial reports with the SEC.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2014–65 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2014–65. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2014–65 and should be submitted on or before January 7, 2015.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29498 Filed 12–16–14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73820; File No. SR–NASDAQ–2014–111]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify a Level 2 Professional Subscriber Fee

December 11, 2014

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 28, 2014, The NASDAQ Stock Market LLC (''NASDAQ'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASDAQ proposes to modify the NASDAQ Level 2 Professional Subscriber (''Subscriber'') fee. While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on January 1, 2015.

* * * * *

7023. NASDAQ Depth-of-Book Data

(a) No change.

(b) Subscriber Fees.

(1) NASDAQ Level 2.

(A) Non-Professional Subscribers pay a monthly fee of $9 each;

(B) Professional Subscribers pay a monthly fee of $[4]5*0* each for Display Usage based upon Direct or Indirect Access, or for Non-Display Usage based upon Indirect Access only;

(C)–(E) No Change.

(2)–(4) No change.

(c)–(e) No change.

* * * * *

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to increase the NASDAQ Level 2 Professional Subscriber fee (''Level 2 fee''). Specifically, the Exchange proposes to increase the Level 2 fee by $5 from $45 to $50 for display usage based upon direct or indirect access, or for non-display usage based upon indirect access only. This proposed rule change will not affect the pricing of the NASDAQ OpenView Non-Professional and Professional Subscriber fees.

The NASDAQ Level 2 product is completely optional. NASDAQ has enhanced this product through capacity upgrades and regulatory data sets over the last approximately 30 years and the release of a new (more efficient) binary version this year. The network capacity for NASDAQ Level 2 has increased from a 56 Kb feed in 1983 to the current 33 Mb feed. Additionally, since NASDAQ Level 2 is also used for market making functions, NASDAQ has invested over the years to add regulatory data sets, such as Market Maker Mode, Trading Action status, Limit Up—Limit Down, Market Wide Circuit Breaker (MWCB) messaging, Short Sale Threshold Indicator, as well as other regulatory information.

In 2014 NASDAQ expanded the reference data available for each security. Level 2 had also been improved with the release this year to give more transparency on Issue Classification and associated Issue Sub-Type, as well as the IPO flag and the flags to help further identify exchange traded products. Additionally, NASDAQ is taking steps to increase resiliency with the upcoming additional back-up feed (also referred to as the ''B'' feed) in the Carteret co-location facility. This helps to reduce cost for customers by receiving both the ''A'' feed and ''B'' feed from the same co-location facility while retaining an additional ''B'' feed out of the mid-Atlantic co-location facility to reduce proximity risk.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides an equitable allocation of reasonable fees among Subscribers and recipients of NASDAQ data and is not designed to permit unfair discrimination between them. NASDAQ's proposal to increase the Level 2 fee by $5 from $45 to $50 for display usage based upon direct or indirect access, or for non-display usage based upon indirect access only, is also consistent with the Act in that it reflects an equitable allocation of reasonable fees. The Commission has long recognized the fair and equitable and not unreasonably discriminatory nature of assessing different fees for Professional and Non-Professional Users of the same data. NASDAQ also believes it is equitable to assess a higher fee per Professional User than to an ordinary Non-Professional User due to the enhanced flexibility, lower overall costs and value that it offers Distributors.

In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public.

The Commission concluded that Regulation NMS—by deregulating the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[5]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to broker-dealers at all, it follows

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4) and (5).

[5] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

that the price at which such data is sold should be set by the market as well. Level 2 is precisely the sort of market data products that the Commission envisioned when it adopted Regulation NMS.

The decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoaliton* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010) (''*NetCoalition I''*), upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for market data. ''In fact, the legislative history indicates that the Congress intended that the market system 'evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed' and that the SEC wield its regulatory power 'in those situations where competition may not be sufficient,' such as in the creation of a 'consolidated transactional reporting system.' *NetCoaltion I,* at 535 (quoting H.R. Rep. No. 94–229, at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 321, 323).

NASDAQ believes that the allocation of the proposed fee is fair and equitable in accordance with Section 6(b)(4) of the Act, and not unreasonably discriminatory in accordance with Section 6(b)(5) of the Act. As described above, the proposed fee is based on pricing conventions and distinctions that exist in NASDAQ's current fee schedule. These distinctions are each based on principles of fairness and equity that have helped for many years to maintain fair, equitable, and not unreasonably discriminatory fees, and that apply with equal or greater force to the current proposal.

As described in greater detail below, if NASDAQ has calculated improperly and the market deems the proposed fees to be unfair, inequitable, or unreasonably discriminatory, firms can discontinue the use of their data because the proposed product is entirely optional to all parties. Firms are not required to purchase data and NASDAQ is not required to make data available or to offer specific pricing alternatives for potential purchases. NASDAQ can discontinue offering a pricing alternative (as it has in the past) and firms can discontinue their use at any time and for any reason (as they often do), including due to their assessment of the reasonableness of fees charged. NASDAQ continues to establish and revise pricing policies aimed at increasing fairness and equitable allocation of fees among Subscribers.

NASDAQ believes that periodically it must adjust the Subscriber fees to reflect market forces. NASDAQ believes it is an appropriate time to adjust this fee to more accurately reflect the investments made to enhance this product through capacity upgrades and regulatory data sets added. This also reflects that the market for this information is highly competitive and continually evolves as products develop and change.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Notwithstanding its determination that the Commission may rely upon competition to establish fair and equitably allocated fees for market data, the *NetCoalition* court found that the Commission had not, in that case, compiled a record that adequately supported its conclusion that the market for the data at issue in the case was competitive. NASDAQ believes that a record may readily be established to demonstrate the competitive nature of the market in question.

There is intense competition between trading platforms that provide transaction execution and routing services and proprietary data products. Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. Data products are valuable to many end Subscribers only insofar as they provide information that end Subscribers expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, an exchange's customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A broker-dealer will direct orders to a particular exchange only if the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the broker-dealer chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the broker-dealer will choose not to buy it. Moreover, as a broker-dealer chooses to direct fewer orders to a particular exchange, the value of the product to that broker-dealer decreases, for two reasons. First, the product will contain less information, because executions of the broker-dealer's orders will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that broker-dealer because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the broker-dealer is directing orders will become correspondingly more valuable.

Thus, an increase in the fees charged for either transactions or data has the potential to impair revenues from both products. ''No one disputes that competition for order flow is 'fierce'.'' *NetCoalition* at 24. However, the existence of fierce competition for order flow implies a high degree of price sensitivity on the part of broker-dealers with order flow, since they may readily reduce costs by directing orders toward the lowest-cost trading venues. A broker-dealer that shifted its order flow from one platform to another in response to order execution price differentials would both reduce the value of that platform's market data and reduce its own need to consume data from the disfavored platform. Similarly, if a platform increases its market data fees, the change will affect the overall cost of doing business with the platform, and affected broker-dealers will assess whether they can lower their trading costs by directing orders elsewhere and thereby lessening the need for the more expensive data.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus, because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among trading platforms can be expected to constrain the aggregate return each platform earns from the sale of its joint products, but different platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some platforms may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower rebates (or no rebates) to attract orders, setting relatively high prices for market information, and setting relatively low prices for accessing posted liquidity. In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering. This would be akin to strictly regulating the price that an automobile manufacturer can charge for car sound systems despite the existence of a highly competitive market for cars and the availability of after-market alternatives to the manufacturer-supplied system.

The market for market data products is competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market.

Broker-dealers currently have numerous alternative venues for their order flow, including thirteen self-regulatory organization (''SRO'') markets, as well as internalizing broker-dealers (''BDs'') and various forms of alternative trading systems (''ATSs''), including dark pools and electronic communication networks (''ECNs''). Each SRO market competes to produce transaction reports via trade executions, and two FINRA-regulated Trade Reporting Facilities (''TRFs'') compete to attract internalized transaction reports. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products.

The large number of SROs, TRFs, BDs, and ATSs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including NASDAQ, New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC, NYSE Arca LLC, and BATS Exchange, Inc. (''BATS'').

Any ATS or BD can combine with any other ATS, BD, or multiple ATSs or BDs to produce joint proprietary data products. Additionally, order routers and market data vendors can facilitate single or multiple broker-dealers' production of proprietary data products. The potential sources of proprietary products are virtually limitless.

The fact that proprietary data from ATSs, BDs, and vendors can by-pass SROs is significant in two respects. First, non-SROs can compete directly with SROs for the production and sale of proprietary data products, as BATS and Arca did before registering as exchanges by publishing data on the Internet. Second, because a single order or transaction report can appear in an SRO proprietary product, a non-SRO proprietary product, or both, the data available in proprietary products is exponentially greater than the actual number of orders and transaction reports that exist in the marketplace.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end Subscribers. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Thomson Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end Subscribers will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: They can simply refuse to purchase any proprietary data product that fails to provide sufficient value. NASDAQ and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN and BATS Trading. A proliferation of dark pools and other ATSs operate profitably with fragmentary shares of consolidated market volume.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While broker-dealers have previously published their proprietary data individually, Regulation NMS encourages market data vendors and broker-dealers to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, and Thomson Reuters.

The vigor of competition for information is significant. NASDAQ has made a determination to adjust the fees associated with this product in order to reflect more accurately the value of its products and the investments made to enhance them, as well as to keep pace with changes in the industry and evolving customer needs. This product is entirely optional and is geared towards attracting new customers, as well as retaining existing customers.

The Exchange has witnessed competitors creating new products and innovative pricing in this space over the course of the past year. NASDAQ continues to see firms challenge its pricing on the basis of the Exchange's explicit fees being higher than the zero-priced fees from other competitors such as BATS. In all cases, firms make decisions on how much and what types of data to consume on the basis of the total cost of interacting with NASDAQ or other exchanges. Of course, the explicit data fees are but one factor in a total platform analysis. Some competitors have lower transactions fees and higher data fees, and others are vice versa. The market for this information is highly competitive and continually evolves as products develop and change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[6] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2014–111 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2014–111. This file number should be included on the subject line if email is used.

To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NASDAQ–2014–111, and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29497 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(a)[sic](ii).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73815; File No. SR–NASDAQ–2014–121]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify NASDAQ Rule 7021 Fees

December 11, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 5, 2014, The NASDAQ Stock Market LLC (''NASDAQ'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

NASDAQ is proposing to modify fees assessed under NASDAQ Rule 7021 for the NasdaqTrader.com Trading and Compliance Data Package (''Data Package''). While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on January 2, 2015.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available at *nasdaq.cchwallstreet.com* at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ is proposing to amend Rule 7021 to increase the fee assessed for subscription to the Data Package and eliminate a little-used report.[3] The Data Package allows member firms to obtain information regarding their own historical quoting and trading activity on NASDAQ. The Data Package also provides member firms with information concerning their compliance with NASDAQ and FINRA rules. When NASDAQ last increased the fees for the Data Package in February 2012,[4] the service provided subscribers the following reports: Monthly Compliance Report Cards, which outline a firm's own compliance with various FINRA rules; Monthly Summaries, which provide monthly trading volume statistics for the top 50 market participants broken down by industry sector, security or type of trading; and Historical Research Reports, which provide a variety of historical trading data such as a market maker's quote updates, order activity, and detailed trade reporting information. Additionally, NASDAQ offered subscribers the ability to receive the detailed trade report (Equity Trade Journal) via a secure FTP dissemination as an option. These reports, which continue to be offered as part of Data Package, are based on the subscribing member firm's historical trade

[3] The Data Package is also commonly referred to as the Report Center.

[4] *See* Securities Exchange Act Release No. 66078 (January 3, 2012), 77 FR 1125 (January 9, 2012) (SR–NASDAQ–2011–173).

information taken from NASDAQ and the FINRA/NASDAQ Trade Reporting Facility.

NASDAQ has continued to enhance what is offered in the Data Package to make it a more useful tool to member firms.[5] In this regard, NASDAQ now provides the following new historical reports, which do not count toward the 25 and 100 monthly report limits under the rule when accessed: Execution Invoice Detail, which provides a member firm with enhanced detail of its executions; Month to Date Invoice Summary, which provides a member firm with a summary of its trading at any point in the month; Excessive Messaging Invoice Detail, which informs a member firm of whether its order activity at any point in a month will qualify for the Excess Order Fee under Rule 7018(m); Investor Support Program Invoice Detail, which informs a member firm of whether its order activity at any point in the month will qualify for the Investor Support Program under Rule 7014; and Qualified Market Maker Invoice Detail, which informs a member firm of whether its order activity at any point in the month will qualify for the Qualified Market Maker Program under Rule 7014. In addition, NASDAQ has enhanced the service with the following new reports, which do count toward the 25 and 100 monthly report limits under the rule when accessed: NASDAQ Order Execution and Routing, which provides a detailed daily summary of a member firm's executions on NASDAQ and those routed to other markets; Market Recap, which provides a daily snapshot in a timeline format of all market events occurring during the day, such as trading halts and limit up/limit down pauses; QView[6] Historical Reports, which provide both daily and monthly summaries of trading based on volume, routing strategy, and order type; and Real-Time Registered Market Maker Report, which provides a market maker with a real-time assessment of whether it is meeting its market making obligations in the securities for which it is a market maker. NASDAQ is also proposing to eliminate the Monthly Compliance Report Card report from the service. NASDAQ notes that the report is not used significantly by subscribers to the service. In addition to having very little demand, the Monthly Compliance Report Card is similar to reports offered by FINRA at no cost.[7] NASDAQ currently offers two monthly Data Package subscriptions: a basic subscription of $175 providing up to 25 reports per month; and a premium subscription of $225 providing up to 100 reports per month. As noted above, NASDAQ last increased the fee for Data Package in February 2012,[8] and since then has enhanced the service with several new reports noted above. NASDAQ is proposing to increase the monthly fee assessed for up to 100 reports from $225 to $250 to cover the costs associated with enhancing and offering the service, and to ensure that the service continues to provide NASDAQ with a profit. In addition to increasing the fee assessed for the 100 report subscription, NASDAQ is proposing to eliminate the basic level subscription. As described above, NASDAQ has substantially increased the number of reports available to subscribers, including those that count against the monthly report limits of the two fee tiers. As a consequence, NASDAQ has observed that the lower tier provides an inadequate number of reports to be useful to most subscribers. Accordingly, NASDAQ is proposing to eliminate the lower tier.

Lastly, NASDAQ is proposing to rename the service as the NASDAQ Report Center. NASDAQ notes that the service is commonly referred to as the Report Center, and changing the name to reflect the commonly-used name will avoid any market participant confusion caused by the two names. Moreover, NASDAQ believes that the proposed new name is more reflective of the nature of the service.

2. *Statutory Basis*

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[9] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[10] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

NASDAQ believes that the proposed increase to the fee assessed under the rule is reasonable because it will allow NASDAQ to realign the fees assessed for the service with the costs it incurs in offering and enhancing it, while also ensuring that NASDAQ continues to realize a profit. The Exchange notes that it has substantially enhanced the service since the last time the fee was increased. Moreover, eliminating the lower tier is reasonable because NASDAQ has observed that the 25 report limit is too low for most member firms given the expansion of reports available to them through the service. As a consequence, the lower tier has limited applicability, yet represents a cost to NASDAQ in monitoring and administering the fee in relation to a subscriber's usage.

NASDAQ believes that the increased fee and elimination of the lower fee tier is an equitable allocation because the increased fee will apply to all subscribers uniformly. NASDAQ notes that under the proposed changes member firms currently subscribing to the lower tier will experience a greater fee increase than those currently subscribing to the higher tier. NASDAQ believes elimination of the lower tier is equitable because the limited number of member firms that subscribe to the lower tier will receive the benefit of a substantially increased monthly report limit.

The Exchange believes that the proposed changes are not unfairly discriminatory because they now apply a uniform fee per subscription, thus eliminating a distinction made in the fee assessed based on the number of reports available per month. The Exchange notes that some member firms may incur a disproportionate increase in fees as compared to others under the proposed change as a result of the elimination of the lower tier subscription. The Exchange does not believe that this change is unfairly discriminatory because it eliminates a distinction in the fee assessed based on the number of reports, which is of declining applicability and use, and provides all member firms with the same level of service at the same cost.

[5] *See http://www.nasdaqtrader.com/trader.aspx?id=reportcenter.*

[6] QView provides a member firm with the ability to track its order flow on NASDAQ, and view both real-time data and download reports of such order flow. *See* Rule 7058. Data Package offers QView historical data, but not real-time reports of order flow.

[7] FINRA offers Equity Report Cards, which allow firms to track their compliance with equity trading rules related to OATS, best execution, market order timeliness, trade reporting, Reg NMS Trade Throughs, and the NASDAQ Market Center. *See http://www.finra.org/Industry/Compliance/ReportCenter/P015063.*

[8] *Supra* note 4.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4) and (5).

As noted, NASDAQ incurs costs in monitoring a subscribing member firm's report limit and in administering the fee. Consequently, reducing the number of fee tiers will reduce NASDAQ's costs, thereby allowing NASDAQ to keep the fee lower than it would otherwise be. In addition, NASDAQ does not believe that elimination of the Monthly Compliance Report Card reports from the service is unfairly discriminatory. As noted, the report is used very little by subscribing member firms and any member firm that seeks similar information may obtain similar reports from FINRA at no cost.

Lastly, NASDAQ believes that the proposed name change will avoid any market participant confusion due to the name of the service used in the rule and the commonly-used name. NASDAQ notes that the proposed change does not affect what is offered by the service in any way.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.[11] NASDAQ notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, NASDAQ must carefully balance the fees it assesses with the costs incurred to remain competitive with other exchanges. To the extent NASDAQ's fees are too high or another exchange's products and services provide greater value, NASDAQ will likely lose subscriber revenue. As such, NASDAQ believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In this instance, NASDAQ last increased the Data Package fees in February 2012 and NASDAQ is now realigning the fee assessed for the subscription to the service with the costs it incurs in offering it. Such costs include adding enhancements to the service to make it more useful to subscribers. Moreover, increasing the fees also allows NASDAQ to continue to derive a profit from the service, which will allow NASDAQ to continue to offer the service in the long term. Moreover, NASDAQ believes that the fee increase does not impose a burden on competition because the service is optional and member firms may develop their own alternatives to the service or acquire similar functionality through third parties. For these reasons, NASDAQ does not believe that the proposed changes will impose any unnecessary burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing change has become effective pursuant to Section 19(b)(3)(A) of the Act,[12] and paragraph (f)[13] of Rule 19b–4, thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2014–121 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2014–121. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2014–121, and should be submitted on or before January 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–29511 Filed 12–16–14; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f).

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before January 16, 2015.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: Lenders requesting SBA to purchase the guaranty portion of a loan are required to supply the Agency with a certified transcript of the loan account. This form is uniform and convenient means for lenders to report and certify loan accounts to purchase by SBA. The Agency uses the information to determine date of loan default and whether Lender disbursed and serviced the loan according to Loan Guaranty agreement.

Solicitation of Public Comment

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections

(1) *Title:* Lender's Transcript of Account.

Description of Respondents: SBA Lenders.

Form Number: SBA Form 1149.

Estimated Annual Respondents: 3,600.

Estimated Annual Responses: 3,600.

Estimated Annual Hour Burden: 36,000.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2014–29471 Filed 12–16–14; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before January 16, 2015.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: The objective of the debt collection activities is to obtain immediate repayment or arrive at a satisfactory arrangement for future repayment of debts owed to the Government. SBA uses the financial information provided by the debtor on Form 770 in making a determination regarding the compromise of such debts and other liquidation proceedings including litigation by the Agency and/or the Department of Justice.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections

(1) *Title:* Financial Statement of Debt.

Description of Respondents: SBA Lenders.

Form Number: SBA Form 770.

Estimated Annual Respondents: 5,000.

Estimated Annual Responses: 5,000.

Estimated Annual Hour Burden: 5,000.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2014–29469 Filed 12–16–14; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

RLJ Credit Opportunity Fund I, L.P. License No. 03/03–0256; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that RLJ Credit Opportunity Fund I, L.P., 3 Bethesda Metro Center, Suite 1000, Bethesda, MD 20814, a Federal Licensee under the Small Business Investment Act of 1958, as amended (the ''Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). RLJ Credit Opportunity Fund I, L.P. has provided debt financing to Naylor, LLC, 5950 NW 1st Place, Gainesville, FL 32607. The proceeds were used to finance the acquisition of Boxwood Technology, Inc.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because RLJ Equity Partners Fund I, L.P., an Associate of RLJ Credit Opportunity Fund I, L.P., owns more than ten percent of Naylor, LLC, and therefore this transaction is considered a financing to an Associate requiring SBA prior written exemption.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for the Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Dated: December 10, 2014.

Javier E. Saade,

Associate Administrator for Office of Investment and Innovation.

[FR Doc. 2014–29518 Filed 12–16–14; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration (''SBA'') under Section 309 of the Small Business Investment Act of 1958, as amended, and Section 107.1900 of the Small Business Administration Rules and Regulations, SBA by this notice declares null and void the license to function as a small business investment company under the Small Business Investment Company

License No. 06/06–0325 issued to Jefferson Capital Partners I, L.P.

United States Small Business Administration.

Dated: December 10, 2014.

Javier E. Saade,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2014–29517 Filed 12–16–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 8975]

In the Matter of the Review of the Designation of Palestinian Islamic Jihad as a Foreign Terrorist Organization Pursuant to Section 219 of the Immigration and Nationality Act

Based upon a review of the Administrative Record assembled in this matter pursuant to Section 219(a)(4)(C) and (b) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C), (b)) (''INA''), and in consultation with the Attorney General and the Secretary of the Treasury, the Secretary of State concludes that the circumstances that were the basis for the 2008 decision to maintain the designation of the aforementioned organization as a foreign terrorist organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation of Palestinian Islamic Jihad.

Therefore, the Secretary of State hereby determines that the designation of the aforementioned organization as a foreign terrorist organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: December 5, 2014.

John F. Kerry,

Secretary of State.

[FR Doc. 2014–29599 Filed 12–16–14; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice 8976]

U.S. Department of State Advisory Committee on Private International Law (ACPIL): Public Meeting on the Hague Trusts Convention

The Office of the Assistant Legal Adviser for Private International Law in the Department of State gives notice of a public meeting to discuss the Convention on the Law Applicable to Trusts and on Their Recognition, which was done at The Hague on July 1, 1985 (hereinafter ''Hague Trusts Convention'' or ''Convention''). The public meeting will take place on Wednesday, January 21, 2015, from 10:30 a.m. until 12:30 p.m. EST. This is not a meeting of the full Advisory Committee.

The purpose of the public meeting is to assess the current level of interest among domestic stakeholders in the Hague Trusts Convention. The Convention was signed on behalf of the United States on June 13, 1988, but the United States is not a party. Eleven countries, in whole or in part, are parties to the Convention, including most common-law jurisdictions and a small number of civil-law countries in Europe.

The Office of the Assistant Legal Adviser for Private International Law is considering whether U.S. ratification of the Convention would be beneficial, as part of a more general initiative to try to address the domestic implementation of private international law treaties. For example, it would be useful to learn of the types of issues that may be confronted by those persons involved in handling trusts that have cross-border aspects, and the potential impact that the Convention would have on these issues.

Time and Place: The meeting will take place from 10:30 a.m. until 12:30 p.m. EST on January 21, in Room 240, South Building, State Department Annex 4, Washington, DC 20037. Participants should plan to arrive at the Navy Hill gate on the west side of 23rd Street NW., at the intersection of 23rd Street NW., and D Street NW., by 10:00 a.m. for visitor screening. If you are unable to attend the public meeting and would like to participate from a remote location, teleconferencing will be available. Those who cannot attend but wish to comment are welcome to do so by email to John Kim at *kimmjj@state.gov.*

Public Participation: This meeting is open to the public, subject to the capacity of the meeting room. Access to the building is strictly controlled. For pre-clearance purposes, those planning to attend should email *pil@state.gov* providing full name, address, date of birth, citizenship, driver's license or passport number, and email address. This information will greatly facilitate entry into the building. A member of the public needing reasonable accommodation should email *pil@state.gov* not later than January 14, 2015. Requests made after that date will be considered, but might not be able to be fulfilled. If you would like to participate by telephone, please email *pil@state.gov* to obtain the call-in number and other information.

Data from the public is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities.

The data will be entered into the Visitor Access Control System (VACS–D) database. Please see the Security Records System of Records Notice (State–36) at *http://www.state.gov/documents/organization/103419.pdf* for additional information.

Dated: December 5, 2014.

John J. Kim,

Assistant Legal Adviser, Office of Private International Law, Office of the Legal Adviser, U.S. Department of State.

[FR Doc. 2014–29596 Filed 12–16–14; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice 8977]

Overseas Schools Advisory Council Notice of Meeting

The Overseas Schools Advisory Council, Department of State, will hold its Annual Committee Meeting on Thursday, January 22, 2015, at 9:30 a.m. in Conference Room 1105, Department of State Building, 2201 C Street NW., Washington, DC. The meeting is open to the public and will last until approximately 12:00 p.m.

The Overseas Schools Advisory Council works closely with the U.S. business community in improving those American-sponsored schools overseas that are assisted by the Department of State and attended by dependents of U.S. Government employees, and the children of employees of U.S. corporations and foundations abroad.

This meeting will deal with issues related to the work and the support provided by the Overseas Schools Advisory Council to the American-sponsored overseas schools. There will be a report and discussion about the status of the Council-sponsored project to expand the World Virtual School. The Regional Education Officers in the Office of Overseas Schools will make a presentations on the activities and initiatives in the American-sponsored overseas schools.

Members of the public may attend the meeting and join in the discussion, subject to the instructions of the Chair. Admittance of public members will be

limited to the seating available. Access to the State Department is controlled, and individual building passes are required for all attendees. Persons who plan to attend should advise the office of Dr. Keith D. Miller, Department of State, Office of Overseas Schools, telephone 202–261–8200, prior to January 15, 2015. Each visitor will be asked to provide his/her date of birth and either driver's license or passport number at the time of registration and attendance, and must carry a valid photo ID to the meeting.

Personal data is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities. The data will be entered into the Visitor Access Control System (VACS–D) database. Please see the Security Records System of Records Notice (State–36) at *http://www.state.gov/documents/organization/103419.pdf* for additional information.

Any requests for reasonable accommodation should be made at the time of registration. All such requests will be considered, however, requests made after January 20th might not be possible to fill. All attendees must use the C Street entrance to the building.

Dated: December 9, 2014.

Keith D. Miller,

Executive Secretary, Overseas Schools Advisory Council.

[FR Doc. 2014–29598 Filed 12–16–14; 8:45 am]

BILLING CODE 4710–24–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Additional Participants in Trade in Services Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: On January 15, 2013, the Office of the United States Trade Representative (USTR) notified Congress of the Administration's intention to enter into negotiations for a Trade in Services Agreement (TISA) with an initial group of 20 trading partners. The January 15 notification states that the group negotiating TISA ''will expand as negotiations progress to include others who share our ambitious goals.'' On November 3, 2014, USTR notified Congress of the Administration's intention to join a consensus reached among the TISA negotiating participants to accept Uruguay into the negotiations. Through this notice, USTR seeks public comments regarding particular priorities with respect to the participation of Uruguay in the negotiations. Comments may be provided in writing.

DATES: Written comments are due by noon, January 20, 2015.

ADDRESSES: *Submissions via on-line: http://www.regulations.gov.* For alternatives to on-line submissions please contact Yvonne Jamison at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Yvonne Jamison at (202) 395–3475. All other questions regarding this notice should be directed to Christopher Melly at (202) 395–4510.

SUPPLEMENTARY INFORMATION: On January 15, 2013, the USTR notified Congress of the Administration's intention to enter into the TISA negotiations. The following 22 trading partners are currently participating in TISA negotiations: Australia, Canada, Chile, Chinese Taipei, Colombia, Costa Rica, European Union on behalf of its member states, Hong Kong China, Iceland, Israel, Japan, Korea, Lichtenstein, Mexico, New Zealand, Norway, Pakistan, Panama, Paraguay, Peru, Switzerland, and Turkey. Comments received through that process may be reviewed at *http://www.regulations.gov* under docket number USTR–2014–0001. On November 3, 2014, the USTR notified Congress of the Administration's intention to join a consensus reached among the TISA negotiating participants to accept Uruguay into the negotiations.

The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing U.S. objectives with regard to Uruguay's potential participation in the negotiations. The TPSC Chair invites comments on all relevant matters, and, in particular, with regard to the nature of any existing barriers to trade in services with respect to Uruguay or issues affecting the supply of services to Uruguay through various modes of supply and technologies.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) ''Trade in Services Agreement: New Participant.'' In order to be assured of consideration, comments should be submitted by noon, January 20, 2015. In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *http://www.regulations.gov* Web site. Comments should be submitted under the following docket: USTR 2014–0026. To find the docket, enter the docket number in the ''Enter Keyword or ID'' window at the *http://www.regulations.gov* home page and click ''Search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''Notices'' under ''Document Type'' on the search-results page, and click on the link entitled ''Comment Now!'' (For further information on using the *http://www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on the ''Help'' tab.)

The *http://www.regulations.gov* Web site provides the option of making submissions by filling in a ''Type Comment'' field, or by attaching a document using the ''Upload File'' field. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type ''See attached'' in the ''Type Comment'' field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the ''Comments'' field. For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character ''P.'' The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments. Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the

same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www.regulations.gov,* if at all possible. Any alternative arrangements must be made with Yvonne Jamison in advance of transmitting a comment. Ms. Jamison should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov.*

Public Inspection of Submissions

Comments will be placed in the docket and open to public inspection, except business confidential information. Comments may be viewed on the *http://www.regulations.gov* Web site by entering the relevant docket number in the search field on the home page.

Douglas Bell,

Chair, Trade Policy Staff Committee.

[FR Doc. 2014–29577 Filed 12–16–14; 8:45 am]

BILLING CODE 3290–F5–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for Waiver for Aeronautical Land-Use Assurance at New Braunfels Regional Airport, New Braunfels, TX

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent for waiver of aeronautical land-use.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal to change a portion of the airport from aeronautical use to nonaeronautical use and to authorize the conversion of the airport property. The proposal consists of one parcel of land containing a total of approximately 3.09 acres located on the east side of the airport, along FM 758.

The parcel was originally acquired as federal surplus property in 1969. The land comprising this parcel is outside the forecasted need for aviation development and, thus, is no longer needed for indirect or direct aeronautical use. The airport wishes to develop this land for compatible commercial, nonaeronautical use. The income from the conversion of this parcel will benefit the aviation community by reinvestment in the airport.

Approval does not constitute a commitment by the FAA to financially assist in the conversion of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA. The disposition of proceeds from the conversion of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999. In accordance with Section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

DATES: Comments must be received on or before January 16, 2015.

ADDRESSES: Send comments on this document to Mr. Edward N. Agnew, Federal Aviation Administration, Manager, Texas Airports Development Office, 2601 Meacham Boulevard, Fort Worth, TX 76137.

FOR FURTHER INFORMATION CONTACT: Mr. Vinicio Llerena, Airport Director, City of New Braunfels, 2333 FM 758, New Braunfels, TX 78130, telephone (830) 221–4295, or Mr. Anthony Mekhail, Federal Aviation Administration, Texas Airports Development Program Manager, 2601 Meacham Boulevard, Fort Worth, TX 76137, telephone (817) 222–5663, FAX (817) 222–5989. Documents reflecting this FAA action may be reviewed at the above locations.

Issued in Fort Worth, Texas, on December 5, 2014.

Edward N. Agnew,

Acting Manager, Airports Division, FAA, Southwest Region.

[FR Doc. 2014–29269 Filed 12–16–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0032]

Commercial Driver's License Standards: Application for Exemption; Daimler Trucks North America (Daimler)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Daimler Trucks North America (Daimler) has requested an exemption for one commercial motor vehicle (CMV) driver, Martin Zeilinger, from the Federal requirement to hold a commercial driver's license (CDL) issued by one of the States. This project engineer holds a valid German CDL and wants to test-drive Daimler vehicles on U.S. roads to better understand product requirements for these systems in ''real world'' environments, and verify results. Daimler believes the requirements for a German CDL ensure that holders of the license will likely achieve a level of safety equal to or greater than that of drivers who hold a U.S. State-issued CDL.

DATES: Comments must be received on or before January 16, 2015.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2012–0032 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–2012–0032 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: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: *MCPSD@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from 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 granting or denying the exemption, 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 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)).

Since 2012, FMCSA has granted four Daimler drivers similar exemptions [May 25, 2012 (77 FR 31422); July 22, 2014 (79 FR 42626); August 29, 2014 (79 FR 51641)]. Each of these drivers held a valid German CDL but lacked the U.S. residency required to obtain a CDL. FMCSA has concluded that the process for obtaining a German CDL is comparable to or as effective as the U.S. CDL requirements and ensures that these drivers will likely achieve a level of safety equivalent to or greater than the level that would be obtained in the absence of the exemption.

Request for Exemption

Daimler has applied for an exemption for one of its engineers from 49 CFR 383.23, which prescribes licensing requirements for drivers operating CMVs in interstate or intrastate commerce. This driver, Martin Zeilinger, holds a valid German CDL but is unable to obtain a CDL in any of the U.S. States due to residency requirements. A copy of the application is in Docket No. FMCSA–2012–0032.

The exemption would allow Mr. Zeilinger to operate CMVs in interstate or intrastate commerce to support Daimler field tests designed to meet future vehicle safety and environmental requirements and to develop improved safety and emission technologies. According to Daimler, Mr. Zeilinger will typically drive for no more than 6 hours per day for 2 consecutive days, and 10 percent of the test driving will be on two-lane State highways, while 90 percent will be on interstate highways. The driving will consist of no more than 200 miles per day, for a total of 400 miles during a two-day period on a quarterly basis. He will in all cases be accompanied by a holder of a U.S. CDL who is familiar with the routes to be traveled. Daimler requests that the exemption cover a two-year period.

FMCSA has determined that the process for obtaining a German CDL is comparable to the Federal requirements of 49 CFR part 383 and adequately assesses a driver's ability to operate CMVs in the United States.

Request for Comments

In accordance with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA requests public comment on Daimler's application for an exemption from the CDL requirements of 49 CFR 383.23. The Agency will consider all comments received by close of business on January 16, 2015. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: December 4, 2014.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2014–29067 Filed 12–16–14; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD–2014–0156]

Request for Comments on a New Information Collection

AGENCY: Maritime Administration, DOT.

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 September 23, 2014 (79 FR 56849).

DATES: Comments must be submitted on or before January 16, 2015.

FOR FURTHER INFORMATION CONTACT: Nuns Jain, Program Excellence & Quality Assurance Group (MAR–600.6), Maritime Administration, U.S. Department of Transportation, 7737 Hampton Boulevard, Building 19, Suite 300, Norfolk, VA 23505, (757) 322–5801 or Email: *nuns.jain@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Quarterly Readiness Reporting of Strategic Seaport Facilities.

OMB Control Number: 2133—NEW.

Type of Request: New Information Collection.

Abstract: Pursuant to the Defense Production Act of 1950, as amended (Pub. L. 111–67), EO 13603, E.O. 12656 and 46 CFR part 340, MARAD works with the DoD to ensure national defense preparedness. Accordingly, MARAD issues a pre-emergency Port Planning Order (PPO) to each Department of Defense (DoD) designated strategic commercial seaport in order to provide the DoD port facilities in support of military deployments during national emergencies. The proposed collection of quarterly information is necessary to validate each port's ability to provide the PPO delineated facilities to the DoD within the PPO delineated time frame. In a February 2, 2014 report entitled *STRATEGIC SEAPORTS: Opportunities Exist to Improve Interagency Coordination, Readiness Reporting, and Port Preparedness,* the Government Accounting Office (GAO) recommended that MARAD collect DoD required readiness data from the strategic commercial ports. This information will be used by MARAD to assist DoD in establishing overall contingency plans necessary to meet national emergency preparedness requirements.

Affected Public: Strategic Commercial Seaports with MARAD Port Planning Orders.

Estimated Number of Respondents: 16.

Estimated Number of Responses: 64.

Annual Estimated Total Annual Burden Hours: 64.

Frequency of Collection: Quarterly.

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: December 11, 2014.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2014–29468 Filed 12–16–14; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35882]

Watco Holdings, Inc.—Continuance in Control Exemption—Bogalusa Bayou Railroad, L.L.C.

Watco Holdings, Inc. (Watco), a noncarrier, has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of Bogalusa Bayou Railroad, L.L.C. (BBRR), upon BBRR's becoming a Class III rail carrier. Watco owns, indirectly, 100 percent of the issued and outstanding stock of BBRR, a limited liability company.

This transaction is related to a concurrently filed verified notice of exemption in *Bogalusa Bayou Railroad—Acquisition of Trackage Rights Exemption Containing Interchange Commitment—Illinois Central Railroad,* Docket No. FD 35880, wherein BBRR seeks Board approval to acquire overhead trackage rights over a one-mile rail line owned by Illinois Central Railroad Company extending between milepost 68.85, at Leescreek, La., and milepost 69.85, at Bogalusa, La.

The transaction may be consummated on or after December 31, 2014, the effective date of the exemption (30 days after the verified notice of exemption was filed).

Watco currently controls, indirectly, one Class II rail carrier that operates in two states and 29 Class III rail carriers that collectively operate in 20 states. For a complete list of these rail carriers, and the states in which they operate, see Watco's verified notice of exemption filed on December 1, 2014. The verified notice is available on the Board's Web site at *WWW.STB.DOT.GOV*.

Watco represents that: (1) The rail lines to be operated by BBRR do not connect with any of the rail lines operated by the carriers in the Watco corporate family; (2) the transaction is not a part of a series of anticipated transactions that would result in such a connection; and (3) the transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Watco states that the purpose of the transaction is to reduce overhead expenses, coordinate billing, maintenance, mechanical, and personnel policies and practices of its rail carrier subsidiaries, and thereby improve the overall efficiency of rail service provided by the railroads in the Watco corporate family.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Because the transaction involves the control of one Class II and one or more Class III rail carriers, the transaction is subject to the labor protection requirements of 49 U.S.C. 11326(b) and *Wisconsin Central Ltd.—Acquisition Exemption—Lines of Union Pacific Railroad,* 2 S.T.B. 218 (1997).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed by December 24, 2014 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35882, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Karl Morell, Ball Janik LLP, 655 Fifteenth Street NW., Suite 225, Washington, DC 20005.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV*.

Decided: December 12, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2014–29550 Filed 12–16–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35880]

Bogalusa Bayou Railroad, L.L.C.—Acquisition of Trackage Rights Exemption Containing Interchange Commitment—Illinois Central Railroad Company

Bogalusa Bayou Railroad, L.L.C. (BBRR),[1] a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire overhead trackage rights over a one-mile rail line owned by Illinois Central Railroad Company (IC) extending between milepost 68.85, at Leescreek, La., and milepost 69.85, at Bogalusa, La., pursuant to an agreement between BBRR and IC.

This transaction is related to a concurrently filed verified notice of exemption in *Watco Holdings, Inc.—Continuance in Control Exemption—Bogalusa Bayou Railroad,* Docket No. FD 35882, wherein Watco Holdings, Inc., seeks Board approval under 49 CFR 1180.2(d)(2) to continue in control of BBRR, upon BBRR's becoming a Class III rail carrier.

BBRR states that the agreement precludes BBRR from interchanging traffic with a third party. As required under 49 CFR 1150.33(h)(1), BBRR has provided additional information concerning the interchange commitment.

BBRR has certified that its projected annual revenues as a result of this transaction will not result in BBRR's becoming a Class II or Class I rail carrier and will not exceed $5 million.

This transaction may be consummated on or after December 31, 2014, the effective date of the exemption (30 days after the verified notice of exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 24, 2014

[1] BBRR is a wholly owned subsidiary of Watco Holdings, Inc.

(at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35880 must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Karl Morell, Ball Janik LLP, 655 Fifteenth Street NW., Suite 225, Washington, DC 20005.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV*

Decided: December 12, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clerk Clearance.

[FR Doc. 2014–29549 Filed 12–16–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF VETERANS AFFAIRS

MyVA Advisory Committee; Notice of Establishment

As required by Section 9(a)(2) of the Federal Advisory Committee Act, the Department of Veterans Affairs hereby gives notice of the establishment of the Department of Veterans Affairs (VA) MyVA Advisory Committee. The Secretary of Veterans Affairs has determined that establishing the Committee is both necessary and in the public interest.

The Committee will advise the Secretary and the Executive Director, MyVA Task Force on matters affecting the MyVA initiative and VA's ability to:

- Rebuild Trust with Veterans and other Stakeholders
- Improve Service Delivery, Focusing on Veteran Outcomes
- Set the Course for Longer-term Excellence and Reform

The Secretary has determined that these functions cannot be performed by VA, an existing committee, or other through other means.

Committee members will be appointed by the Secretary's authorized designee and will be drawn from various venues and organization types such as Veteran-focused organizations, health sciences and academic communities, organizational leadership and change management groups, State/Local/Tribal Governments, health care administrators and leaders of key stakeholder associations and organizations. Additionally, two individuals will be recommended as ex-officio members.

Any member of the public seeking additional information should contact Sharon Stevens (40A1), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, District of Columbia, or email at *Sharon.Stevens@va.gov;* or via phone at (202) 461–6013.

Dated: December 12, 2014.

Rebecca Schiller,

Federal Advisory Committee Management Officer.

[FR Doc. 2014–29551 Filed 12–16–14; 8:45 am]

BILLING CODE 8310–01–P

FEDERAL REGISTER

Vol. 79 Wednesday,
No. 242 December 17, 2014

Part II

Environmental Protection Agency

40 CFR Parts 50, 51, 52, et al.

National Ambient Air Quality Standards for Ozone; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 52, 53, and 58

[EPA–HQ–OAR–2008–0699; FRL–9918–43–OAR]

RIN 2060–AP38

National Ambient Air Quality Standards for Ozone

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: Based on its review of the air quality criteria for ozone (O_3) and related photochemical oxidants and national ambient air quality standards (NAAQS) for O_3, the Environmental Protection Agency (EPA) proposes to make revisions to the primary and secondary NAAQS for O_3 to provide requisite protection of public health and welfare, respectively. The EPA is proposing to revise the primary standard to a level within the range of 0.065 to 0.070 parts per million (ppm), and to revise the secondary standard to within the range of 0.065 to 0.070 ppm, which air quality analyses indicate would provide air quality, in terms of 3-year average W126 index values, at or below a range of 13–17 ppm-hours. The EPA proposes to make corresponding revisions in data handling conventions for O_3 and conforming changes to the Air Quality Index (AQI); to revise regulations for the prevention of significant deterioration (PSD) program to add a transition provision for certain applications; and to propose schedules and convey information related to implementing any revised standards. The EPA is proposing changes to the O_3 monitoring seasons, the Federal Reference Method (FRM) for monitoring O_3 in the ambient air, Federal Equivalent Method (FEM) procedures for testing, and the Photochemical Assessment Monitoring Stations (PAMS) network.

Along with proposing exceptional event schedules related to implementing any revised O_3 standards, the EPA is proposing to apply this same schedule approach to other future revised NAAQS and to remove obsolete regulatory language for expired exceptional event deadlines. The EPA is proposing to make minor changes to the procedures and time periods for evaluating potential FRMs and equivalent methods (including making the requirements for nitrogen dioxide consistent with the requirements for O_3) and to remove an obsolete requirement for the annual submission of documentation by manufacturers of certain particulate matter monitors. For additional information, see the Executive Summary, section I.A.

DATES: Written comments on this proposed rule must be received by March 17, 2015.

Public Hearings: The EPA intends to hold three public hearings on this proposed rule in January 2015. These will be announced in a separate **Federal Register** notice that provides details, including specific dates, times, addresses, and contact information for these hearings.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2008–0699, to the EPA by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Email: A-and-R-Docket@epa.gov*. Include docket ID No. EPA–HQ–OAR–2008–0699 in the subject line of the message.
- *Fax:* (202) 566–9744.
- *Mail:* Environmental Protection Agency, EPA Docket Center (EPA/DC), Mailcode 28221T, Attention Docket ID No. OAR–2008–0699, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of two copies.
- *Hand/Courier Delivery:* EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Ave. NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2008–0699. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information 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 the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: The EPA has established dockets for these actions as discussed above. All documents in these dockets are listed on the *www.regulations.gov* Web site. This includes documents in the rulemaking docket (Docket ID No. EPA–HQ–OAR–2008–0699) and a separate docket, established for the Integrated Science Assessment (ISA) (Docket No. EPA–HQ–ORD–2011–0050) that has have been incorporated by reference into the rulemaking docket. 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, is not placed on the Internet and may be viewed, with prior arrangement, at the EPA Docket Center. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742. For additional information about EPA's public docket visit the EPA Docket Center homepage at: *http://www.epa.gov/epahome/dockets.htm*.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Lyon Stone, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504–06, Research Triangle Park, NC 27711; telephone: (919) 541–1146; fax: (919) 541–0237; email: *stone.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to the EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of documents relevant to this rulemaking are available on EPA Web sites. The ISA for Ozone and Related Photochemical Oxidants is available on the EPA's National Center for Environmental Assessment (NCEA) Web site. To obtain this document, go to *http://www.epa.gov/ncea*, and click on Ozone in the Quick Finder section. This will open a page with a link to the February 2013 ISA. The 2014 Policy Assessment (PA), Health and Welfare Risk and Exposure Assessments (HREA and WREA, respectively), and other related technical documents are available on EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site. The final 2014 PA is available at: *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_pa.html*, and the final 2014 Health and Welfare Risk and Exposure Assessments and other related technical documents are available at: *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_rea.html*. These and other related documents are also available for inspection and copying in the EPA docket identified above.

Environmental Justice

Analyses evaluating the potential implications of a revised O_3 NAAQS for environmental justice populations are discussed in appendix 9A of the Regulatory Impact Analysis (RIA) that accompanies this notice of proposed rulemaking. The RIA is available on the Web, through the EPA's Technology Transfer Network Web site at *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html*.

Table of Contents

The following topics are discussed in this preamble:

I. Background

A. Executive Summary

This section summarizes information about the purpose of this regulatory action (I.A.1), the major provisions of this proposal (I.A.2), and provisions related to implementation (I.A.3).

1. Purpose of This Regulatory Action

Sections 108 and 109 of the Clean Air Act (CAA) govern the establishment, review, and revision, as appropriate, of the NAAQS to protect public health and welfare. The CAA requires the EPA to periodically review the air quality criteria—the science upon which the standards are based—and the standards themselves. This rulemaking is being conducted pursuant to these statutory requirements. The schedule for completing this review is established by a federal court order, which requires that the EPA sign a proposal by December 1, 2014, and make a final determination by October 1, 2015.

The EPA completed its most recent review of the O_3 NAAQS in 2008. As a result of that review, EPA took four principal actions: (1) Revised the level of the 8-hour primary O_3 standard to 0.075 parts per million (ppm); (2) expressed the standard to three decimal places; (3) revised the 8-hour secondary O_3 standard by making it identical to the revised primary standard; and (4) made conforming changes to the AQI for O_3.

In subsequent litigation, the U.S. Court of Appeals for the District of Columbia Circuit upheld the EPA's 2008 primary O_3 standard, but remanded the 2008 secondary standard. *State of Mississippi* v. *EPA,* 744 F. 3d 1334 (D.C. Cir. 2013). With respect to the primary standard, the court held that the EPA reasonably determined that the existing primary standard, set in 1997, did not protect public health with an adequate margin of safety and required revision. In upholding the EPA's revised primary standard, the court dismissed arguments that the EPA should have adopted a more stringent standard. The court remanded the secondary standard to the EPA after rejecting the EPA's explanation for setting the secondary standard identical to the revised 8-hour primary standard. The court held that because the EPA had failed to identify a level of air quality requisite to protect public welfare, the EPA's comparison between the primary and secondary standards for determining if requisite protection for public welfare was afforded by the primary standard failed to comply with the CAA.

This proposal reflects the Administrator's proposed conclusions based on a review of the O_3 NAAQS that began in September 2008. In conducting this review, the EPA has carefully evaluated the currently available scientific literature on the health and welfare effects of ozone, focusing particularly on the new literature available since the conclusion of the previous review in 2008. In addition, the EPA has also addressed the remand of the Agency's 2008 decision on the secondary standard. Between 2008 and 2014, the EPA prepared draft and final versions of the Integrated Science Assessment, the Health and Welfare Risk and Exposure Assessments, and the Policy Assessment. Multiple drafts of these documents were available for public review and comment, and as required by the CAA, were peer-reviewed by the Clean Air Scientific Advisory Committee (CASAC), an independent scientific advisory committee established by the CAA and charged with providing advice to the Administrator. The final documents reflect the EPA staff's consideration of the comments and recommendations made by CASAC and the public on draft versions of these documents.

2. Summary of Major Provisions

The EPA is proposing that the current primary O_3 standard set at a level of 0.075 ppm is not requisite to protect public health with an adequate margin of safety, and that it should be revised to provide increased public health protection. Specifically, the EPA is proposing to retain the indicator (ozone), averaging time (8-hour) and form (annual fourth-highest daily maximum, averaged over 3 years) of the existing primary O_3 standard and is proposing to revise the level of that standard to within the range of 0.065 ppm to 0.070 ppm. The EPA is proposing this revision to increase public health protection, including for ''at-risk'' populations such as children, older adults, and people with asthma or other lung diseases, against an array of O_3-related adverse health effects. For short-term O_3 exposures, these effects include decreased lung function, increased respiratory symptoms and pulmonary inflammation, effects that result in serious indicators of respiratory morbidity such as emergency department visits and hospital admissions, and all-cause (total nonaccidental) mortality. For long-term O_3 exposures, these health effects include a variety of respiratory morbidity effects and respiratory mortality. Recognizing that the CASAC recommended a range of levels from 0.060 ppm to 0.070 ppm, and that levels as low as 0.060 ppm could potentially be supported, the Administrator solicits comment on alternative standard levels below 0.065 ppm, and as low as 0.060 ppm. However, the Administrator notes that setting a standard below 0.065 ppm, down to 0.060 ppm, would inappropriately place very little weight on the uncertainties in the health effects evidence and exposure/risk information. Given alternative views of the currently available evidence and information expressed by some commenters, the EPA is taking comment on both the Administrator's proposed decision to revise the current primary O_3 standard and the option of retaining that standard.

In addition to proposing changes to the level of the standard, the EPA is

proposing conforming changes to the Air Quality Index (AQI) by proposing to set an AQI value of 100 equal to the level of the 8-hour primary O_3 standard, and proposing adjustments to the AQI values of 50, 150, 200 and 300.

The EPA also proposes to revise the secondary standard to provide increased protection against vegetation-related effects on public welfare. As an initial matter, the Administrator proposes to conclude that air quality in terms of a three-year average seasonal W126 index value, based on the three consecutive month period within the O_3 season with the maximum index value, with daily exposures cumulated for the 12-hour period from 8:00 a.m. to 8:00 p.m., within the range from 13 ppm-hrs to 17 ppm-hrs would provide the requisite protection against known or anticipated adverse effects to the public welfare. The EPA solicits comment on this proposed conclusion. In considering how to achieve that level of air quality, the Administrator recognizes that air quality data analyses suggest that air quality in terms of three-year average W126 index values of a range at or below 13 to 17 ppm-hrs would be provided by a secondary standard level within the range of 0.065 to 0.070 ppm, and that to the extent areas need to take action to attain a standard in the range of 0.065 to 0.070 ppm, those actions would also improve air quality as measured by the W126 metric. Thus, the Administrator proposes to revise the level of the current secondary standard to within the range of 0.065 to 0.070 ppm. The EPA solicits comments on this proposed revision of the secondary standard.

The EPA also solicits comments on the alternative approach of revising the secondary standard to a W126-based form, averaged over three years, with a level within the range of 13 ppm-hrs to 17 ppm-hrs. The EPA additionally solicits comments on such a distinct secondary standard with a level within the range extending below 13 ppm-hrs down to 7 ppm-hrs. Further, the EPA solicits comments on retaining the current secondary standard without revision, along with the alternative views of the evidence that would support retaining the current standard.

3. Provisions Related to Implementation

As directed by the CAA, reducing pollution to meet national air quality standards always has been a shared task, one involving the federal government, states, tribes and local air agencies. This partnership has proved effective since the EPA first issued O_3 standards more than three decades ago, and is evidenced by significantly lower O_3 levels throughout the country. To provide a foundation that helps air agencies build successful strategies for attaining new O_3 standards, the EPA will continue to move forward with federal regulatory programs, such as the proposed Clean Power Plan and the final Tier 3 motor vehicle emissions standards. To facilitate the development of CAA-compliant implementation plans and strategies to attain new standards, the EPA intends to issue timely and appropriate implementation guidance and, where appropriate and consistent with the law, new rulemakings to streamline regulatory burdens and provide flexibility in implementation. In addition, given the regional nature of O_3 air pollution, the EPA will continue to work with states to address interstate transport of O_3 and O_3 precursors.

This notice contains several proposed provisions related to implementation of the proposed standards. In addition to revisions to the primary and secondary NAAQS, the EPA is proposing to make corresponding revisions in data handling conventions for O_3; to revise regulations for the Prevention of Significant Deterioration (PSD) permitting program to add a provision grandfathering certain pending permits from certain requirements with respect to the proposed revisions to the O_3 NAAQS; and to convey schedules and information related to implementing any revised standards.

In conjunction with proposing exceptional event schedules related to implementing any revised O_3 standards, the EPA is also proposing to extend the new schedule approach to other future revised NAAQS and to remove obsolete regulatory language associated with expired exceptional event deadlines for historical standards for both O_3 and other NAAQS pollutants. The EPA is also proposing to make minor changes to the procedures and time periods for evaluating potential FRMs and equivalent methods, including making the requirements for nitrogen dioxide consistent with the requirements for O_3, and removing an obsolete requirement for the annual submission of documentation by manufacturers of certain particulate matter monitors.

B. Legislative Requirements

Two sections of the CAA govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her ''judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;'' ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;'' and ''for which . . . [the Administrator] plans to issue air quality criteria . . . .'' Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . . .'' 42 U.S.C. 7408(b). Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See *State of Mississippi* v. *EPA,* 744 F. 3d 1334, 1353 (D.C. Cir. 2013) (''By requiring an 'adequate margin of safety', Congress was directing EPA to build a buffer to protect against uncertain and unknown dangers to human health''); see *also Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980); *American Petroleum Institute* v. *Costle,*

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,'' and that, for this purpose, ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

665 F.2d 1176, 1186 (D.C. Cir. 1981); *American Farm Bureau Federation* v. *EPA,* 559 F. 3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers* v. *EPA,* 604 F. 3d 613, 617–18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentrations, see *Lead Industries* v. *EPA,* 647 F.2d at 1156 n.51; *State of Mississippi* v. *EPA,* 744 F. 3d at 1351, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects, the size of sensitive population(s)[3] at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach for providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association* v. *EPA,* 647 F.2d at 1161–62; *State of Mississippi,* 744 F. 3d at 1353.

In setting primary and secondary standards that are ''requisite'' to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, the EPA may not consider the costs of implementing the standards. See generally, *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001). Likewise, ''[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.'' *American Petroleum Institute* v. *Costle,* 665 F. 2d at 1185.

Section 109(d)(1) requires that ''not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . .'' Section 109(d)(2) requires that an independent scientific review committee ''shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . .'' Since the early 1980's, the Clean Air Scientific Advisory Committee (CASAC) has performed this independent review function.[4]

C. Related Control Programs To Implement O_3 Standards

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 of the CAA, and related provisions, states are to submit, for the EPA's approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the PSD program (CAA sections 160 to 169). In addition, federal programs provide for nationwide reductions in emissions of O_3 precursors and other air pollutants through the federal motor vehicle and motor vehicle fuel control program under title II of the CAA (sections 202 to 250) which involves controls for emissions from mobile sources and controls for the fuels used by these sources, and new source performance standards for stationary sources under section 111 of the CAA. For some stationary sources, the national emissions standards for hazardous air pollutants under section 112 of the CAA may provide ancillary reductions in O_3 precursors.

After the EPA establishes a new or revised NAAQS, the CAA directs the EPA and the states to take steps to ensure that the new or revised NAAQS is met. One of the first steps, known as the initial area designations, involves identifying areas of the country that either are attaining or not attaining the new or revised NAAQS along with the nearby areas that contribute to the violations. Upon designation of nonattainment areas, certain states would then be required to develop SIPs to attain the standards. In developing their attainment plans, states would first take into account projected emission reductions from federal and state rules that have been already adopted at the time of plan submittal. A number of significant emission reduction programs that will lead to reductions of O_3 precursors are in place today or are expected to be in place by the time any new SIPs will be due. Examples of such rules include the Nitrogen Oxides (NO_X) SIP Call, Clean Air Interstate Rule (CAIR), and Cross-State Air Pollution Rule (CSAPR),[5] regulations controlling onroad and nonroad engines and fuels, the utility and industrial boilers hazardous air pollutant rules, and various other programs already adopted by states to reduce emissions from key emissions sources. States would then evaluate the level of additional emission reductions needed for each nonattainment area to attain the O_3 standards ''as expeditiously as practicable,'' and adopt new state regulations as appropriate. Section VII of this preamble includes additional discussion of designation and implementation issues associated with any revised O_3 NAAQS.

D. Review of Air Quality Criteria and Standards for O_3

The EPA first established primary and secondary NAAQS for photochemical oxidants in 1971 (36 FR 8186, April 30, 1971). The EPA set both primary and secondary standards at a level of 0.08 parts per million (ppm), 1-hr average, total photochemical oxidants, not to be exceeded more than one hour per year. The EPA based the standards on scientific information contained in the 1970 *Air Quality Criteria for Photochemical Oxidants* (U.S. DHEW, 1970). The EPA initiated the first periodic review of the NAAQS for photochemical oxidants in 1977. Based on the 1978 *Air Quality Criteria for Ozone and Other Photochemical Oxidants* (U.S. EPA, 1978), the EPA published proposed revisions to the original NAAQS in 1978 (43 FR 16962) and final revisions in 1979 (44 FR 8202). At that time, the EPA revised the level of the primary and secondary standards from 0.08 to 0.12 ppm and changed the

[3] As used here and similarly throughout this document, the term ''population'' refers to people having a quality or characteristic in common, including a specific pre-existing illness or a specific age or life stage.

[4] Lists of CASAC members and of members of the CASAC Ozone Review Panel are available at: *http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubCommittees/Ozone%20Review%20Panel*.

[5] The Cross-State Air Pollution Rule was recently upheld by the Supreme Court in *Environmental Protection Agency* v. *EME Homer City Generation,* U.S. (2014). The DC Circuit has since lifted the stay of the rule. Order, Document #1518738, *EME Homer City Generation, L.P.* v. *EPA,* Case #11–1302 (D.C. Cir. Oct. 23, 2014).

indicator from photochemical oxidants to O_3, and the form of the standards from a deterministic (*i.e.,* not to be exceeded more than one hour per year) to a statistical form. This statistical form defined attainment of the standards as occurring when the expected number of days per calendar year with maximum hourly average concentration greater than 0.12 ppm equaled one or less.

Following the final decision in the 1979 review, the City of Houston challenged the Administrator's decision arguing that the standard was arbitrary and capricious because natural O_3 concentrations and other physical phenomena in the Houston area made the standard unattainable in that area. The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) rejected this argument, holding (as noted above) that attainability and technological feasibility are not relevant considerations in the promulgation of the NAAQS. The court also noted that the EPA need not tailor the NAAQS to fit each region or locale, pointing out that Congress was aware of the difficulty in meeting standards in some locations and had addressed this difficulty through various compliance related provisions in the CAA. See *API* v. *Costle,* 665 F.2d 1176, 1184–6 (D.C. Cir. 1981).

In 1982, the EPA announced plans to revise the 1978 Air Quality Criteria document (47 FR 11561), and in 1983, the EPA initiated the second periodic review of the O_3 NAAQS (48 FR 38009). The EPA subsequently published the 1986 *Air Quality Criteria for Ozone and Other Photochemical Oxidants* (U.S. EPA, 1986) and the 1989 Staff Paper (U.S. EPA, 1989). Following publication of the 1986 Air Quality Criteria Document (AQCD), a number of scientific abstracts and articles were published that appeared to be of sufficient importance concerning potential health and welfare effects of O_3 to warrant preparation of a Supplement (U.S. EPA, 1992). On August 10, 1992, under the terms of a court order, the EPA published a proposed decision to retain the existing primary and secondary standards (57 FR 35542). The notice explained that the proposed decision would complete the EPA's review of information on health and welfare effects of O_3 assembled over a 7-year period and contained in the 1986 AQCD and its 1992 Supplement. The proposal also announced the EPA's intention to proceed as rapidly as possible with the next review of the air quality criteria and standards for O_3 in light of emerging evidence of health effects related to 6- to 8-hour O_3 exposures. On March 9, 1993, the EPA concluded the review by affirming its proposed decision to retain the existing primary and secondary standards (58 FR 13008).

In August 1992, the EPA announced plans to initiate the third periodic review of the air quality criteria and O_3 NAAQS (57 FR 35542). In December 1996, the EPA proposed to replace the then-existing 1-hour primary and secondary standards with 8-hour average O_3 standards set at a level of 0.08 ppm (equivalent to 0.084 ppm using standard rounding conventions) (61 FR 65716). The EPA also proposed to establish a new distinct secondary standard using a biologically based cumulative, seasonal form. The EPA completed this review on July 18, 1997 (62 FR 38856) by setting the primary standard at a level of 0.08 ppm, based on the annual fourth-highest daily maximum 8-hr average concentration, averaged over three years, and setting the secondary standard identical to the revised primary standard. In reaching this decision, the EPA identified several reasons supporting its decision to reject a potential alternate standard set at 0.07 ppm. Most importantly, the EPA pointed out the scientific uncertainty at lower concentrations and placed significant weight on the fact that no CASAC panel member supported a standard level set lower than 0.08 ppm (62 FR 38868). In addition to noting the uncertainties in the health evidence for exposure concentrations below 0.08 ppm and the advice of CASAC, the EPA noted that a standard set at a level of 0.07 ppm would be closer to peak background concentrations that infrequently occur in some areas due to nonanthropogenic sources of O_3 precursors (62 FR 38856, 38868; July 18, 1997).

On May 14, 1999, in response to challenges by industry and others to the EPA's 1997 decision, the D.C. Circuit remanded the O_3 NAAQS to the EPA, finding that section 109 of the CAA, as interpreted by the EPA, effected an unconstitutional delegation of legislative authority. *American Trucking Assoc.* v. *EPA,* 175 F.3d 1027, 1034–1040 (D.C. Cir. 1999) (''*ATA I*''). In addition, the court directed that, in responding to the remand, the EPA should consider the potential beneficial health effects of O_3 pollution in shielding the public from the effects of solar ultraviolet (UV) radiation, as well as adverse health effects. *Id.* at 1051–53. In 1999, the EPA petitioned for rehearing *en banc* on several issues related to that decision. The court granted the request for rehearing in part and denied it in part, but declined to review its ruling with regard to the potential beneficial effects of O_3 pollution. 195 F.3d 4, 10 (D.C. Cir., 1999) (''*ATA II*''). On January 27, 2000, the EPA petitioned the U.S. Supreme Court for certiorari on the constitutional issue (and two other issues), but did not request review of the ruling regarding the potential beneficial health effects of O_3. On February 27, 2001, the U.S. Supreme Court unanimously reversed the judgment of the D.C. Circuit on the constitutional issue. *Whitman* v. *American Trucking Assoc.,* 531 U.S. 457, 472–74 (2001) (holding that section 109 of the CAA does not delegate legislative power to the EPA in contravention of the Constitution). The Court remanded the case to the D.C. Circuit to consider challenges to the O_3 NAAQS that had not been addressed by that court's earlier decisions. On March 26, 2002, the D.C. Circuit issued its final decision on remand, finding the 1997 O_3 NAAQS to be ''neither arbitrary nor capricious,'' and so denying the remaining petitions for review. *American Trucking Associations, Inc.* v. *EPA,* 283 F.3d 355, 379 (D.C. Cir., 2002) (''*ATA III*'').

Specifically, in *ATA III,* the D.C. Circuit upheld the EPA's decision on the 1997 O_3 standard as the product of reasoned decision-making. With regard to the primary standard, the court made clear that the most important support for EPA's decision to revise the standard was the health evidence of insufficient protection afforded by the then-existing standard (''the record is replete with references to studies demonstrating the inadequacies of the old one-hour standard''), as well as extensive information supporting the change to an 8-hour averaging time. 283 F.3d at 378. The court further upheld the EPA's decision not to select a more stringent level for the primary standard noting ''the absence of any human clinical studies at ozone concentrations below 0.08 [ppm]'' which supported EPA's conclusion that ''the most serious health effects of ozone are 'less certain' at low concentrations, providing an eminently rational reason to set the primary standard at a somewhat higher level, at least until additional studies become available.'' *Id.* (internal citations omitted). The Court also pointed to the significant weight that the EPA properly placed on the advice it received from CASAC. *Id.* at 379. In addition, the court noted that ''although relative proximity to peak background O_3 concentrations did not, in itself, necessitate a level of 0.08 [ppm], EPA could consider that factor when choosing among the three alternative levels.'' *Id.*

Independently of the litigation, the EPA responded to the court's remand to

consider the potential beneficial health effects of O_3 pollution in shielding the public from effects of UV radiation. The EPA provisionally determined that the information linking changes in patterns of ground-level O_3 concentrations to changes in relevant patterns of exposures to UV radiation of concern to public health was too uncertain, at that time, to warrant any relaxation in 1997 O_3 NAAQS. The EPA also expressed the view that any plausible changes in UV–B radiation exposures from changes in patterns of ground-level O_3 concentrations would likely be very small from a public health perspective. In view of these findings, the EPA proposed to leave the 1997 8-hour NAAQS unchanged (66 FR 57268, Nov. 14, 2001). After considering public comment on the proposed decision, the EPA published its final response to this remand on January 6, 2003, re-affirming the 8-hour O_3 NAAQS set in 1997 (68 FR 614).

The EPA initiated the fourth periodic review of the air quality criteria and O_3 standards in September 2000 with a call for information (65 FR 57810). The schedule for completion of that review was ultimately governed by a consent decree resolving a lawsuit filed in March 2003 by plaintiffs representing national environmental and public health organizations, who maintained that the EPA was in breach of a mandatory legal duty to complete review of the O_3 NAAQS within a statutorily mandated deadline. On July 11, 2007, the EPA proposed to revise the level of the primary standard within a range of 0.075 to 0.070 ppm (72 FR 37818). Documents supporting this proposed decision included the *Air Quality Criteria for Ozone and Other Photochemical Oxidants* (U.S. EPA, 2006a) and the Staff Paper (U.S. EPA, 2007) and related technical support documents. The EPA also proposed two options for revising the secondary standard: (1) Replace the current standard with a cumulative, seasonal standard, expressed as an index of the annual sum of weighted hourly concentrations cumulated over 12 daylight hours during the consecutive 3-month period within the O_3 season with the maximum index value, set at a level within the range of 7 to 21 ppm-hrs, or (2) set the secondary standard identical to the proposed primary standard. The EPA completed the review with publication of a final decision on March 27, 2008 (73 FR 16436). In that final rule, the EPA revised the NAAQS by lowering the level of the 8-hour primary O_3 standard from 0.08 ppm to 0.075 ppm, not otherwise revising the primary standard, and adopting a secondary standard identical to the revised primary standard. In May 2008, state, public health, environmental, and industry petitioners filed suit challenging the EPA's final decision on the 2008 O_3 standards. On September 16, 2009, the EPA announced its intention to reconsider the 2008 O_3 standards, and initiated a rulemaking to do so. At the EPA's request, the Court held the consolidated cases in abeyance pending the EPA's reconsideration of the 2008 decision.

On January 19, 2010 (75 FR 2938), the EPA issued a notice of proposed rulemaking to reconsider the 2008 final decision. In that notice, the EPA proposed that further revisions of the primary and secondary standards were necessary to provide a requisite level of protection to public health and welfare. The EPA proposed to decrease the level of the 2008 8-hour primary standard from 0.075 ppm to a level within the range of 0.060 to 0.070 ppm, and to change the secondary standard to a new cumulative, seasonal standard expressed as an annual index of the sum of weighted hourly concentrations, cumulated over 12 hours per day (8 a.m. to 8 p.m.), during the consecutive 3-month period within the O_3 season with a maximum index value, set at a level within the range of 7 to 15 ppm-hours. The Agency also solicited CASAC review of the proposed rule on January 25, 2010 and solicited additional CASAC advice on January 26, 2011. After considering comments from CASAC and the public, the EPA prepared a draft final rule, which was submitted for interagency review pursuant to Executive Order 12866. On September 2, 2011, consistent with the direction of the President, the Administrator of the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB), returned the draft final rule to the EPA for further consideration. In view of this return and the fact that the Agency's next periodic review of the O_3 NAAQS required under CAA section 109 had already begun (as announced on September 29, 2008), the EPA deferred the decisions involved in the reconsideration until it completed its statutorily required periodic review.

In light of EPA's decision to consolidate the reconsideration with the current review, the D.C. Circuit proceeded with the litigation on the 2008 final decision. On July 23, 2013, the Court upheld the EPA's 2008 primary O_3 standard, but remanded the 2008 secondary standard to the EPA. *State of Mississippi* v. *EPA,* 744 F.3d 1334. With respect to the primary standard, the court first held that the EPA reasonably determined that the existing standard was not requisite to protect public health with an adequate margin of safety, and consequently required revision. Specifically, the court noted that there were ''numerous epidemiologic studies linking health effects to exposure to ozone levels below 0.08 ppm and clinical human exposure studies finding a causal relationship between health effects and exposure to ozone levels at and below 0.08 ppm.'' 744 F.3d at 1345. The court also specifically endorsed the weight of evidence approach utilized by the EPA in its deliberations. *Id.* at 1344.

The court went on to reject arguments that the EPA should have adopted a more stringent primary standard. Dismissing arguments that a clinical study (as properly interpreted by the EPA) showing effects at 0.06 ppm necessitated a standard level lower than that selected, the court noted that this was a single, limited study. *Id.* at 1350. With respect to the epidemiologic evidence, the court accepted the EPA's argument that there could be legitimate uncertainty that a causal relationship between O_3 and 8-hour exposures less than 0.075 ppm exists, so that associations at lower levels reported in epidemiologic studies did not necessitate a more stringent standard. *Id.* at 1351–52.[6]

The court also rejected arguments that an 8-hour primary standard of 0.075 ppm failed to provide an adequate margin of safety, noting that margin of safety considerations involved policy judgments by the agency, and that by setting a standard ''appreciably below'' the level of the current standard (0.08 ppm), the agency had made a reasonable policy choice. *Id.* Finally, the court rejected arguments that the EPA's decision was inconsistent with CASAC's scientific recommendations because CASAC had been insufficiently clear in its recommendations whether it was providing scientific or policy recommendations, and the EPA had reasonably addressed CASAC's policy recommendations. *Id.* at 1357–58.

With respect to the secondary standard, the court held that because the EPA had failed to identify a level of air quality requisite to protect public welfare, the EPA's comparison between

[6] The court cautioned, however, that ''perhaps more [clinical] studies like the Adams studies will yet reveal that the 0.060 ppm level produces significant adverse decrements that simply cannot be attributed to normal variation in lung function,'' and further cautioned that ''agencies may not merely recite the terms 'substantial uncertainty' as a justification for their actions.'' *Id.* at 1350, 1357 (internal citations omitted).

the primary and secondary standards for determining if requisite protection for public welfare was afforded by the primary standard did not comply with the CAA. The court thus rejected the EPA's explanation for setting the secondary standard identical to the revised 8-hour primary standard, and remanded the secondary standard to the EPA. *Id.* at 1360–62.

At the time of the court's decision, the EPA had already completed significant portions of its next statutorily required periodic review of the O_3 NAAQS. On September 29, 2008, the EPA announced the initiation of a new periodic review of the air quality criteria for O_3 and related photochemical oxidants and issued a call for information in the **Federal Register** (73 FR 56581, Sept. 29, 2008). A wide range of external experts, as well as the EPA staff, representing a variety of areas of expertise (*e.g.,* epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science, ecology, biology, plant science, ecosystem services) participated in a workshop. This workshop was held on October 28–29, 2008 in Research Triangle Park, NC. The workshop provided an opportunity for a public discussion of the key policy-relevant issues around which the EPA would structure this O_3 NAAQS review and the most meaningful new science that would be available to inform our understanding of these issues.

Based in part on the workshop discussions, the EPA developed a draft Integrated Review Plan (IRP) outlining the schedule, process, and key policy-relevant questions that would guide the evaluation of the air quality criteria for O_3 and the review of the primary and secondary O_3 NAAQS. A draft of the IRP was released for public review and comment in September 2009. This IRP was the subject of a consultation with the CASAC on November 13, 2009 (74 FR 54562; October 22, 2009).[7] The EPA considered comments received from that consultation and from the public in finalizing the plan and in beginning the review of the air quality criteria. The EPA's overall plan and schedule for this review is presented in the *Integrated Review Plan for the Ozone National Ambient Air Quality Standards*.[8]

As part of the process of preparing the O_3 ISA, the EPA's NCEA hosted a workshop to review and discuss preliminary drafts of key sections of the ISA on August 6, 2010 (75 FR 42085, July 20, 2010). The CASAC and the public reviewed the first external review draft ISA (U.S. EPA, 2011a; 76 FR 10893, February 28, 2011) at a meeting held in May 19–20, 2011 (76 FR 23809; April 28, 2011). Based on CASAC and public comments, NCEA prepared a second draft ISA (U.S. EPA, 2011b; 76 FR 60820, September 30, 2011). CASAC and the public reviewed this draft at a January 9–10, 2012 (76 FR 236, December 8, 2011) meeting. Based on CASAC and public comments, NCEA prepared a third draft ISA (U.S. EPA 2012a; 77 FR 36534; June 19, 2012), which was reviewed at a CASAC meeting in September 2012. The EPA released the final ISA (EPA/600/R–10/076F) in February 2013.

The EPA presented its plans for conducting the Risk and Exposure Assessments (REAs) that build on the scientific evidence presented in the ISA, in two planning documents titled *Ozone National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment* and *Ozone National Ambient Air Quality Standards: Scope and Methods Plan for Welfare Risk and Exposure Assessment* (henceforth, Scope and Methods Plans).[9] These planning documents outlined the scope and approaches that staff planned to use in conducting quantitative assessments, as well as key issues that would be addressed as part of the assessments. The EPA released these documents for public comment in April 2011, and consulted with CASAC on May 19–20, 2011 (76 FR 23809; April 28, 2011). In designing and conducting the initial health risk and welfare risk assessments, the EPA considered CASAC comments (Samet, 2011) on the Scope and Methods Plans and also considered public comments. In May 2012, the EPA issued a memo titled *Updates to Information Presented in the Scope and Methods Plans for the Ozone NAAQS Health and Welfare Risk and Exposure Assessments* that described changes to elements of the scope and methods plans and provided a brief explanation of each change and the reason for it.

In July 2012, the EPA made the first drafts of the Health and Welfare REAs available for CASAC review and public comment (77 FR 42495, July 19, 2012). The first draft PA [10] was made available for CASAC review and public comment in August 2012. These documents were reviewed by the CASAC O_3 Panel at a public meeting in September 2012. The second draft REAs and PA, made available by the EPA in January 2014 (79 FR 4694, January 29, 2014), were prepared with consideration of advice from CASAC (Frey and Samet, 2012a, 2012b) and comments from the public. These drafts were reviewed by the CASAC O_3 Panel at a public meeting on March 25–27, 2014. The CASAC issued final reports on the second drafts of the HREA on July 1, 2014 (Frey, 2014a), and the WREA on June 18, 2014 (Frey, 2014b), respectively. The CASAC issued a final report on the second draft PA on June 26, 2014 (Frey, 2014c). The final versions of the HREA (U.S. EPA 2014a), WREA (U.S. EPA, 2014b), and PA (U.S. EPA, 2014c) were made available by the EPA in August, 2014. These documents reflect staff's consideration of the comments and recommendations made by CASAC, as well as comments made by members of the public, in their review of the draft versions of these documents.

E. Ozone Air Quality

Ozone is formed near the Earth's surface due to chemical interactions involving solar radiation and precursor pollutants including volatile organic compounds (VOCs), nitrogen oxides (NO_X), methane (CH_4) and carbon monoxide (CO). The precursor emissions leading to O_3 formation can result from both man-made sources (*e.g.,* motor vehicles and electric power generation) and natural sources (*e.g.,* vegetation and wildfires). Occasionally, O_3 that is created naturally in the stratosphere can also contribute to O_3 levels near the surface. Once formed, O_3 can be transported by winds before eventually being removed from the atmosphere via chemical reactions or deposition to surfaces. In sum, O_3 concentrations are influenced by complex interactions between precursor emissions, meteorological conditions, and surface characteristics.

In order to continuously assess O_3 air pollution levels, state and local environmental agencies operate O_3 monitors at various locations and

[7] See *http://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsbyTopicCASAC!OpenView* for more information on CASAC activities related to the current O_3 NAAQS review.

[8] EPA 452/R–11–006; April 2011; Available: *http://www.epa.gov/ttn/naaqs/standards/ozone/data/2011_04_OzoneIRP.pdf.*

[9] EPA–452/P–11–001 and -002; April 2011; Available: *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_pd.html.*

[10] The PA is prepared by the staff in the EPA's Office of Air Quality Planning and Standards (OAQPS). It presents a staff evaluation of the policy implications of the key scientific and technical information in the ISA and REAs for the EPA's consideration. The PA provides a transparent evaluation, and staff conclusions, regarding policy considerations related to reaching judgments about the adequacy of the current standards, and if revision is considered, what revisions may be appropriate to consider. The PA is intended to help ''bridge the gap'' between the agency's scientific assessments presented in the ISA and REAs, and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS.

subsequently submit the data to the EPA. At present, there are approximately 1,400 monitors across the U.S. reporting hourly O_3 averages during the times of the year when local O_3 pollution can be important. Much of this monitoring is focused on O_3 measurements in urban areas where precursor emissions tend to be largest, as well as locations directly downwind of these areas, but there are also over 100 sites in rural areas where high levels of O_3 can periodically exist due to transport from upwind sources. Based on data from this national network, the EPA estimates that approximately 133 million Americans live in counties where O_3 concentrations were above the level of the existing health-based NAAQS of 0.075 ppm at least 4 days in 2012. High O_3 values can occur almost anywhere within the contiguous 48 states, although locations in California, Texas, and the Northeast Corridor are especially subject to poor O_3 air quality. From a temporal perspective, the highest daily peak O_3 concentrations generally tend to occur during the afternoon within the warmer months due to higher solar radiation and other conducive meteorological conditions during these times. The exceptions to this general rule include: (1) Some rural sites where transport of O_3 from upwind areas of regional production can occasionally result in high nighttime levels of O_3, (2) high-elevation sites periodically influenced by stratospheric intrusions, and (3) certain locations in the western U.S. where large quantities of O_3 precursors emissions associated with oil and gas development can be trapped by strong inversions associated with snow cover during the colder months and efficiently converted to O_3.

One of the challenging aspects of developing plans to reduce emissions leading to high O_3 concentrations is that the response of O_3 to precursor reductions is nonlinear. In particular, NO_X causes both the formation and destruction of O_3. The net impact of NO_X emissions on O_3 concentrations depends on the local quantities of NO_X, VOC, and sunlight which interact in a set of complex chemical reactions. In some areas, such as urban centers where NO_X emissions typically are high, NO_X leads to the net destruction of O_3, making O_3 levels lower in the immediate vicinity. This phenomenon is particularly pronounced under conditions that lead to low O_3 concentrations (*i.e.* during cool, cloudy weather and at night when photochemical activity is limited or nonexistent). However, while NO_X can initially destroy O_3 near the emission sources, these same NO_X emissions eventually do react to form more O_3 downwind. Photochemical model simulations suggest that the additional expected reductions in NO_X emissions will slightly increase O_3 concentrations on days with lower O_3 concentrations in areas in close proximity to NO_X sources, while at the same time decreasing the highest O_3 concentrations in outlying areas. See generally, U.S. EPA, 2014a (section 2.2.1).

At present, both the primary and secondary NAAQS use the annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years, as the form of the standard. An additional air quality metric, referred to as W126, is often used to assess cumulative impact of O_3 exposure on ecosystems and vegetation. W126 is a seasonal aggregate of weighted hourly O_3 values observed between 8 a.m. and 8 p.m. As O_3 precursor emissions have decreased across the U.S., O_3 design values [11] have concurrently shown a modest downward trend. Ozone design values decreased by approximately 9% on average between 2000 and 2012. Air quality model simulations estimate that peak O_3 levels will continue to improve over the next decade as additional reductions in O_3 precursors from power plants, motor vehicles, and other sources are realized.

In addition to being affected by changing emissions, future O_3 concentrations will also be affected by climate change. Modeling studies in EPA's Interim Assessment (U.S. EPA, 2009b) and cited in support of the 2009 Endangerment Finding (74 FR 66,496; Dec. 15, 2009) show that, while the impact is not uniform, climate change has the potential to cause increases in summertime O_3 concentrations over substantial regions of the country, with increases tending to occur during higher peak pollution episodes in the summer, if offsetting emissions reductions are not made. Increases in temperature are expected to be the principal factor in driving any ozone increases, although increases in stagnation frequency may also contribute (Jacob and Winner, 2009). These increases in O_3 pollution over broad areas of the U.S., including in the largest metropolitan areas with the worst O_3 problems, increase the risk of morbidity and mortality. Children, people with asthma or other lung diseases, older adults, and people who are active outdoors, including outdoor workers, are among the most vulnerable to these O_3-related health effects. If unchecked, climate change has the potential to offset some of the improvements in O_3 air quality, and therefore some of the improvements in public health, that are expected from reductions in emissions of O_3 precursors.

Another challenging aspect of the O_3 issue is the involvement of sources of O_3 and O_3 precursors beyond those from domestic, anthropogenic sources. Modeling analyses have suggested that nationally the majority of O_3 exceedances are predominantly caused by anthropogenic emissions from within the U.S. However, observational and modeling analyses have concluded that O_3 concentrations in some locations in the U.S. can be substantially influenced by sources that may not be suited to domestic control measures. In particular, certain high-elevation sites in the western U.S. are impacted by a combination of non-local sources like international transport, stratospheric O_3, and O_3 originating from wildfire emissions. Ambient O_3 from these non-local sources is collectively referred to as background O_3. See generally section 2.4 of the Policy Assessment (U.S. EPA, 2014c). The analyses suggest that, at these locations, there can be episodic events with substantial background contributions where O_3 concentrations approach or exceed the level of the current NAAQS (*i.e.,* 75 ppb). These events are relatively infrequent and the EPA has policies that allow for the exclusion of air quality monitoring data from design value calculations when they are substantially affected by certain background influences. Wildfires pose a direct threat to air quality and public safety—threats that can be mitigated through management of wildland vegetation. The use of wildland prescribed fire can influence the occurrence of catastrophic wildfires which may help manage the contribution of wildfires to background O_3 levels and periodic peak O_3 events. Prescribed fire mimics a natural process necessary to manage and maintain fire-adapted ecosystems and climate change adaptation, while reducing risk of uncontrolled emissions from catastrophic wildfires. Wildfire emissions may make it more challenging to meet the NAAQS. However, the CAA requires the EPA to set the NAAQS at levels requisite to protect public health and welfare without regard to the source of the pollutant. *API,* 665 F. 2d at 1185–86. The EPA may consider proximity to background levels as a factor in the decision whether and how to revise the NAAQS when considering levels within the range of reasonable values

[11] A design value is a statistic that describes the air quality status of a given location relative to the level of the NAAQS.

supported by the air quality criteria and judgments of the Administrator. *ATA III,* 283 F. 3d at 379. It is in the implementation process that states and the EPA can address how to develop effective public policy in locations in which background sources contribute substantially to high O_3. Section VII.F provides more detail about how background O_3 can be addressed via CAA implementation provisions.

II. Rationale for Proposed Decision on the Primary Standard

This section presents the Administrator's rationale for her proposed decision to revise the existing primary O_3 standard by lowering the level of the standard to within the range of 0.065 to 0.070 ppm. As discussed more fully below, this rationale draws from the thorough review in the ISA of the available scientific evidence, published through July 2011, on human health effects associated with the presence of O_3 in the ambient air. This rationale also takes into account: (1) Analyses of O_3 air quality, human exposures to O_3, and O_3-associated health risks, as presented and assessed in the HREA; (2) the EPA staff assessment of the most policy-relevant scientific evidence and exposure/risk information in the PA; (3) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA, REA, and PA at public meetings, in separate written comments, and in CASAC's letters to the Administrator; and (4) public input received during the development of these documents, either in connection with CASAC meetings or separately.

Section II.A below provides an overview of the approaches used to consider the scientific evidence and exposure/risk information as it relates to the primary O_3 standard. This includes summaries of the approach adopted by the Administrator in the 2008 review of the O_3 NAAQS and of the approach adopted in the PA in the current review. Section II.B summarizes the body of evidence for health effects attributable to short- or long-term O_3 exposures, with a focus on effects for which the ISA judges that there is a ''causal'' or a ''likely to be causal'' relationship with O_3 exposures. Section II.C summarizes the HREA's quantitative estimates of O_3 exposures and health risks, including key results and uncertainties. Sections II.D and II.E present the Administrator's proposed conclusions on the adequacy of the current primary O_3 standard and alternative primary standards, respectively.

A. Approach

In the 2008 review of the O_3 NAAQS, Administrator Stephen L. Johnson revised the level of the 8-hour primary O_3 standard from 0.08 ppm [12] to 0.075 ppm (75 parts per billion (ppb) [13]). This decision was based on his consideration of the available scientific evidence and exposure/risk information, the advice and recommendations of CASAC, and comments from the public. The Administrator placed primary emphasis on the body of available scientific evidence, while viewing the results of exposure and risk assessments as providing supporting information. Specifically, he judged that a standard set at 75 ppb would be appreciably below the concentration at which adverse effects had been demonstrated in the controlled human exposure studies available at that time (*i.e.,* 80 ppb), and would provide a significant increase in protection compared to the then-current standard. The Administrator further concluded that the body of evidence did not support setting a lower standard level, given the increasing uncertainty in the evidence at lower O_3 concentrations (U.S. EPA, 2014c, Chapter 1).

In the current review, the EPA's approach to informing decisions on the primary O_3 standard builds upon the general approach used in the last review and reflects the broader body of scientific evidence, updated exposure/risk information, and advances in O_3 air quality modeling now available. This approach, described in detail in the PA (U.S. EPA, 2014c, section 1.3.1), is based most fundamentally on using the EPA's assessment of the available scientific evidence and associated quantitative analyses to inform the Administrator's judgments regarding a primary standard for O_3 that is ''requisite'' (*i.e.,* neither more nor less stringent than necessary) to protect public health with an adequate margin of safety. Specifically, it is based on consideration of the available body of scientific evidence assessed in the ISA (U.S. EPA, 2013a), exposure and risk analyses presented in the HREA (U.S. EPA, 2014a), advice and recommendations from CASAC (Frey, 2014a, c), and public comments. Based on the application of this approach, the PA assesses and integrates the evidence and information, and reaches conclusions for the Administrator's consideration about the range of policy options that could be supported. The remainder of this section describes the PA's approach to reviewing the primary O_3 standard, and to informing the Administrator's proposed decisions on the current and alternative standards.

As an initial matter, the PA recognizes that the final decision to retain or revise the current primary O_3 standard is a public health policy judgment to be made by the Administrator and will draw upon the available scientific evidence for O_3-attributable health effects and on analyses of population exposures and health risks, including judgments about the appropriate weight to assign the range of uncertainties inherent in the evidence and analyses. The PA's general approach to informing these public health policy judgments recognizes that the available health effects evidence reflects a continuum from relatively higher O_3 concentrations, at which scientists generally agree that health effects are likely to occur, through lower concentrations, at which the likelihood and magnitude of a response become increasingly uncertain. Therefore, the conclusions in the PA reflect an interpretation of the available scientific evidence and exposure/risk information that, in the views of the EPA staff, neither overstates nor understates the strengths and limitations of that evidence and information.[14] This approach is consistent with the requirements of sections 108 and 109 of the CAA, as well as with how the EPA and the courts have historically interpreted the CAA.

The PA draws upon an integrative synthesis of the entire body of available scientific evidence for O_3-related health effects, including the evidence newly available in the current review and the evidence from previous reviews, as presented in the ISA (U.S. EPA, 2013a). Consideration of the scientific evidence is based fundamentally on information from controlled human exposure and epidemiologic studies, supplemented by information from animal toxicology studies. In the PA, such evidence informs the consideration of the health

[12] Due to rounding convention, the 1997 standard level of 0.08 ppm corresponded to 0.084 ppm (84 ppb).

[13] The level of the O_3 standard is specified as 0.075 ppm rather than 75 ppb. However, in the PA we refer to ppb, which is most often used in the scientific literature and in the ISA, in order to avoid the confusion that could result from switching units when discussing the evidence in relation to the standard level. Similarly, in the preamble to this notice we refer to ppb.

[14] Draft versions of the PA were subject to review by CASAC and the final PA reflects consideration of the advice received from CASAC during the review process. CASAC concluded that ''Overall, we find the Second Draft PA to be adequate for its intended purpose of providing a strong scientific basis for findings regarding the inadequacy of current primary and secondary ozone air quality standards'' (Frey, 2014c, p. v).

endpoints and at-risk populations [15] on which to focus the current review, and the consideration of the O_3 concentrations at which various health effects can occur.

Since the 2008 review of the O_3 NAAQS, the EPA has developed formal frameworks for characterizing the strength of the scientific evidence with regard to health effects associated with exposures to O_3 in ambient air and factors that may increase risk in some populations or lifestages. These frameworks provide the basis for robust, consistent, and transparent processes for evaluating the scientific evidence, including uncertainties in the evidence, and for drawing weight-of-evidence conclusions on air pollution-related health effects and at-risk populations. These frameworks for characterizing the strength of the scientific evidence are discussed in detail in the ISA (U.S. EPA, 2013a, Preamble; Chapter 8).

With regard to characterization of health effects, the ISA uses a five-level hierarchy to classify the overall weight of evidence into one of the following categories: causal relationship, likely to be a causal relationship, suggestive of a causal relationship, inadequate to infer a causal relationship, and not likely to be a causal relationship (U.S. EPA, 2013a, Preamble Table II). In using the weight-of-evidence approach to inform judgments about the degree of confidence that various health effects are likely to be caused by exposure to O_3, confidence increases as the number of studies consistently reporting a particular health endpoint grows and as other factors, such as biological plausibility and the strength, consistency, and coherence of evidence, increase. Conclusions about biological plausibility and about the consistency and coherence of O_3-related health effects are drawn from the integration of epidemiologic studies with mechanistic information from controlled human exposure and animal toxicological studies, as discussed in the ISA (U.S. EPA, 2013a, EPA Framework for Causal Determination, p. 1viii). The PA places the greatest weight on the health effects for which the evidence has been judged in the ISA to support a ''causal'' or a ''likely to be causal'' relationship with O_3 exposures.

The PA further considers the evidence base assessed in the ISA with regard to the types and levels of exposure at which health effects are indicated. This consideration of the evidence, which directly informs conclusions regarding the adequacy of current or alternative standards, differs from consideration of the evidence in the ISA with regard to overarching determinations of causality. Therefore, studies that inform determinations of causality may or may not be concluded to be informative with regard to the adequacy of the current or alternative standards.[16]

As with health endpoints, the ISA's characterization of the weight of evidence for potential at-risk populations is based on the evaluation and synthesis of evidence from across scientific disciplines. The ISA uses the collective evidence to examine the coherence of effects across disciplines and to determine the biological plausibility of reported effects. Based on this approach, the ISA characterizes the evidence for a number of ''factors'' that have the potential to place populations at increased risk for O_3-related effects. The categories considered in evaluating the evidence for these potential at-risk factors are ''adequate evidence,'' ''suggestive evidence,'' ''inadequate evidence,'' and ''evidence of no effect.'' For the ''adequate evidence'' category, the ISA concludes that this category is appropriate when multiple high-quality studies show ''there is substantial, consistent evidence within a discipline to conclude that a factor results in a population or lifestage being at increased risk of air pollutant-related health effect(s) relative to some reference population or lifestage'' (U.S. EPA, 2013a, p. 8–2). In addition, where applicable, the ''adequate evidence'' category reflects a conclusion that there is coherence in the evidence across disciplines. The other categories reflect greater uncertainty in the evidence. In this review, the PA focuses on those factors for which the ISA judges there is adequate evidence of increased risk (U.S. EPA, 2013a, Table 8–5). At-risk populations are discussed in more detail in section 3.1.5 of the PA (U.S. EPA, 2014c) and these categories are discussed in more detail in the ISA (U.S. EPA, 2013a, chapter 8, Table 8–1).

Using the available scientific evidence to inform conclusions on the current and alternative standards is complicated by the recognition that a population-level threshold has not been identified below which it can be concluded with confidence that O_3-attributable effects do not occur (U.S. EPA, 2013a, section 2.5.4.4). In the absence of a discernible threshold, the PA's general approach to considering the available O_3 health evidence involves characterizing confidence in the extent to which O_3-attributable effects occur, and the extent to which such effects are adverse, over the ranges of O_3 exposure concentrations evaluated in controlled human exposure studies and over the distributions of ambient O_3 concentrations in locations where epidemiologic studies have been conducted. As noted above, the PA recognizes that the available health effects evidence reflects a continuum from relatively high O_3 concentrations, at which scientists generally agree that adverse health effects are likely to occur, through lower concentrations, at which the likelihood and magnitude of a response become increasingly uncertain. Aspects of the approach used in this review to evaluate evidence from controlled human exposure and epidemiologic studies, respectively, are discussed below.

Controlled human exposure studies provide direct evidence of relationships between pollutant exposures and human health effects (U.S. EPA, 2013a, p.lx). Controlled human exposure studies provide data with the highest level of confidence since they provide human effects data under closely monitored conditions and can provide exposure response relationships. Such studies are particularly useful in defining the specific conditions under which pollutant exposures can result in health impacts, including the exposure concentrations, durations, and ventilation rates under which effects can occur. As discussed in the ISA, controlled human exposure studies provide clear and compelling evidence for an array of human health effects that are directly attributable to acute exposures to O_3 *per se* (*i.e.,* as opposed to O_3 and other photochemical oxidants, for which O_3 is an indicator, or other co-occurring pollutants) (U.S. EPA, 2013a, Chapter 6). Together with animal toxicological studies, which can provide

[15] In this review, the term ''at-risk population'' is used to encompass populations or lifestages that have a greater likelihood of experiencing health effects related to exposure to an air pollutant due to a variety of factors; other terms used in the literature include susceptible, vulnerable, and sensitive. These factors may be intrinsic, such as genetic factors, lifestage, or the presence of preexisting diseases, or they may be extrinsic, such as socioeconomic status (SES), activity pattern and exercise level, or increased pollutant exposures (U.S. EPA 2013, p. lxx, 8–1, 8–2). The courts and the CAA's legislative history refer to these at-risk subpopulations as ''susceptible'' or ''sensitive'' populations. See, *e.g., American Lung Ass'n* v. *EPA,* 134 F. 3d 388, 389 (D.C. Cir. 1998) (''NAAQS must protect not only average health individuals, but also 'sensitive citizens'—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution'' (quoting S. Rep. No. 91–1196 at 10).

[16] For example, the PA judges that health studies evaluating exposure concentrations near or below the level of the current standard and epidemiologic studies conducted in locations meeting the current standard are particularly informative when considering the adequacy of the public health protection provided by the current standard (U.S. EPA, 2014c, Chapters 3 and 4).

information about more serious health outcomes as well as the effects of long-term exposures and mode of action, controlled human exposure studies also help to provide biological plausibility for health effects observed in epidemiologic studies.

The PA considers the evidence from controlled human exposure studies in two ways. First, the PA considers the extent to which controlled human exposure studies provide evidence for health effects following exposures to different O_3 concentrations, down to the lowest-observed-effects levels in those studies. Second, the PA uses these studies to help evaluate the extent to which there is confidence in health effect associations reported in epidemiologic studies down through lower ambient O_3 concentrations, where the likelihood and magnitude of O_3-attributable effects become increasingly uncertain.

The PA considers the range of O_3 exposure concentrations evaluated in controlled human exposure studies, including concentrations near or below the level of the current standard. The PA considers both group mean responses, which provide insight into the extent to which observed changes are due to O_3 exposures rather than to chance alone, and interindividual variability in responses, which provides insight into the fraction of the population that might be affected by such O_3 exposures (U.S. EPA, 2013a, section 6.2.1.1). When considering the relative weight to place on various controlled human exposure studies, the discussion in the PA focuses on the exposure conditions evaluated (*e.g.,* exercising versus resting, exposure duration); the nature, magnitude, and likely adversity of effects over the range of reported O_3 exposure concentrations; the statistical precision of reported effects; and the consistency of results across studies for a given health endpoint and exposure concentration. In addition, because controlled human exposure studies typically involve healthy individuals and do not evaluate the most sensitive individuals in the population (U.S. EPA, 2013a, Preamble p. lx), when considering the implications of these studies for evaluation of the current and alternative standards, the PA also considers the extent to which reported effects are likely to reflect the magnitude and/or severity of effects in at-risk groups.

The PA also considers epidemiologic studies of short- and long-term O_3 concentrations in ambient air. Epidemiologic studies provide information on associations between variability in ambient O_3 concentrations and variability in various health outcomes, including lung function decrements, respiratory symptoms, school absences, hospital admissions, emergency department visits, and premature mortality (U.S. EPA, 2013a, Chapters 6 and 7). Epidemiologic studies can inform understanding of the effects in the study population (which may include at-risk groups) of real-world exposures to the range of O_3 concentrations in ambient air, as well as provide evidence of associations between ambient O_3 levels and more serious acute and chronic health effects that cannot be assessed in controlled human exposure studies. For these studies, the degree of uncertainty introduced by confounding variables (*e.g.*, other pollutants, temperature) and other factors (*e.g.*, effects modifiers such as averting behavior) affects the level of confidence that the health effects being investigated are attributable to O_3 exposures, alone and in combination with copollutants.

Available epidemiologic studies have generally not indicated a discernible population threshold below which O_3 is no longer associated with health effects (U.S. EPA, 2013a, section 2.5.4.4). However, the currently available epidemiologic evidence indicates decreased confidence in reported concentration-response relationships for O_3 concentrations at the lower ends of ambient distributions due to the low density of data in this range (U.S. EPA, 2013a, section 2.5.4.4). As discussed more fully in Chapter 1 of the PA (U.S. EPA, 2014c), the general approach to considering the results of epidemiologic studies within the context of the current and alternative standards focuses on characterizing the range of ambient O_3 concentrations over which studies indicate the most confidence in O_3-associated health effects, and the concentrations below which confidence in such health effect associations becomes appreciably lower.

In placing emphasis on specific epidemiologic studies, as in past reviews, the discussion in the PA focuses on the epidemiologic studies conducted in the U.S. and Canada. Such studies reflect air quality and exposure patterns that are likely more typical of the U.S. population, since studies conducted outside the U.S. and Canada may well reflect different demographic and air pollution characteristics.[17] The PA also focuses on studies reporting associations with effects judged in the ISA (U.S. EPA, 2013a) to be robust to confounding by other factors, including co-occurring air pollutants.

To put staff conclusions about O_3-related health effects into a broader public health context, the PA also considers exposure and risk estimates from the HREA, which develops and applies models to estimate human exposures to O_3 and O_3-related health risks in urban study areas across the United States (U.S. EPA, 2014a). The HREA estimates exposures of concern, based on interpreting quantitative exposure estimates within the context of controlled human exposure study results; lung function risks, based on applying exposure-response relationships from controlled human exposure studies to quantitative estimates of exposures; and epidemiologic-based risk estimates, based on applying concentration-response relationships drawn from epidemiologic studies to adjusted air quality. Each of these types of assessments is discussed briefly below.

As in the 2008 review, the HREA estimates exposures at or above benchmark concentrations of 60, 70, and 80 ppb, reflecting exposure concentrations of concern based on the available health evidence.[18] Estimates of exposures of concern, defined as personal exposures while at moderate or greater exertion to 8-hour average ambient O_3 levels, at or above these discrete benchmark concentrations provide perspective on the public health risks of O_3-related health effects that have been demonstrated in controlled human exposure and toxicological studies. However, because of a lack of exposure-response information across a range of exposure concentrations in these studies, these risks cannot be assessed using a quantitative risk assessment. Though this analysis is conducted using discrete benchmark concentrations, information from the broad body of evidence indicates that health-relevant exposures are more appropriately viewed as a continuum with greater confidence and certainty about the existence of health effects at higher O_3 exposure concentrations and less confidence and certainty at lower exposure concentrations. This approach recognizes that there is no sharp breakpoint within the exposure-response relationship for exposure concentrations at and above 80 ppb down to 60 ppb.

Within the context of this continuum, estimates of exposures of concern at these discrete benchmark

[17] Though the PA recognizes that a broader body of studies, including international studies, informs the causal determinations in the ISA.

[18] For example, see 75 FR 2945–2946 (January 19, 2010) and 73 FR 16441–16442 (March 27, 2008) discussing ''exposures of concern.''

concentrations provide some perspective on the public health impacts of O_3-related health effects, such as pulmonary inflammation, that are plausibly linked to the more serious effects seen in epidemiologic studies but cannot be evaluated in quantitative risk assessments. They also help elucidate the extent to which such impacts may be reduced by meeting the current and alternative standards. Estimates of the number of people likely to experience exposures of concern cannot be directly translated into quantitative estimates of the number of people likely to experience specific health effects due to individual variability in responsiveness. Only a subset of individuals can be expected to experience such adverse health effects, and at-risk populations or lifestages, such as people with asthma or children, are expected to be affected more by such exposures than healthy adults.

The HREA also generates quantitative estimates of O_3 health risks for air quality adjusted to just meet the current [19] and alternative standards. One approach to estimating O_3 health risks is to combine modeled exposure estimates with exposure-response relationships derived from controlled human exposure studies of O_3-induced health effects. The HREA uses this approach to estimate the occurrence of O_3-induced lung function decrements in at-risk populations, including school-age children, school-age children with asthma, adults with asthma, and older adults. The available exposure-response information does not support this approach for other endpoints evaluated in controlled human exposure studies (U.S. EPA, 2014a, section 2.3).

The other approach used in this review to estimate O_3-associated health risks is to apply concentration-response relationships derived from short- and/or long-term epidemiologic studies to air quality adjusted to just meet current and alternative standards. The concentration-response relationships drawn from epidemiologic studies are based on population exposure surrogates, such as 8-hour concentrations averaged across monitors and over more than one day (U.S. EPA, 2013a, Chapter 6). The HREA presents epidemiologic-based risk estimates for O_3-associated mortality, hospital admissions, emergency department visits, and respiratory symptoms (U.S. EPA, 2014a, section 2.3). These estimates are derived from the full distributions of ambient O_3 concentrations estimated for the study locations.[20] In addition, the HREA estimates mortality risks associated with various portions of distributions of short-term O_3 concentrations (U.S. EPA, 2014a). The PA considers risk estimates based on the full distributions of ambient O_3 concentrations and, when available, estimates of the risk associated with various portions of those ambient distributions.[21] In doing so, the PA takes note of the ISA conclusions regarding confidence in linear concentration-response relationships over distributions of ambient concentrations (see above), and of the extent to which health effect associations at various ambient O_3 concentrations are supported by the evidence from experimental studies for effects following specific O_3 exposures.

B. Health Effects Information

This section outlines key information contained in the ISA (U.S. EPA, 2013a, Chapters 4 to 8) and in the PA (U.S. EPA, 2014c, Chapters 3 and 4) on the known or potential effects on public health which may be expected from the presence of O_3 in the ambient air. The information highlighted here summarizes: (1) New information available on potential mechanisms for health effects associated with exposure to O_3 (II.B.1); (2) the nature of effects that have been associated directly with both short- and long-term exposure to O_3 and indirectly with the presence of O_3 in ambient air (II.B.2); (3) considerations related to the adversity of O_3-attributable health effects (II.B.3); and (4) considerations in characterizing the public health impact of O_3, including the identification of ''at risk'' populations (II.B.4).

The decision in the 2008 rulemaking emphasized the large number of epidemiologic studies published since the 1997 review that continued to report associations with respiratory hospital admissions and emergency department visits, as well as additional health endpoints, including the effects of acute (short-term and prolonged) and chronic exposures to O_3 on lung function decrements and enhanced respiratory symptoms in asthmatic individuals, school absences, and premature mortality. It also emphasized controlled human exposure studies showing respiratory effects with prolonged O_3 exposures at levels below 80 ppb, changes in lung host defenses, and increased airway responsiveness, and animal toxicology studies that provided information about mechanisms of action.

The ISA (U.S. EPA, 2013a) prepared for this review emphasizes a large number of new epidemiologic studies published since the last review on effects associated with both short- and long-term exposures, including new epidemiologic studies about risk factors. It also emphasizes important new information from controlled human exposure, dosimetry and toxicology studies. Highlights of the new evidence included:

(1) Two controlled human exposure studies new since the 2008 review are now available that examine respiratory effects associated with prolonged, 6.6-hour, O_3 exposures to levels of 72 ppb [22] and 60 ppb. These studies observed effects in healthy adults, including lung function decrements combined with respiratory symptoms at 72 ppb, and lung function decrements and pulmonary inflammation at 60 ppb. These studies expand on evidence of lung function decrements with O_3 exposure at 60 ppb available in the last review, and provide new evidence of airway inflammation, a mechanism by which O_3 may cause other more serious respiratory effects (*e.g.*, asthma exacerbations).

(2) Recent multicity and single city epidemiologic studies continue to report associations between short-term O_3 exposures and respiratory hospital admissions and respiratory emergency department visits. Recent multicity studies and a multi-continent study have reported consistent positive associations between short-term O_3 exposure and total (nonaccidental) mortality, expanding upon evidence available in the last review. They also observed associations between O_3 exposure and cardiovascular and respiratory mortality.[23]

(3) Recent controlled human exposure studies reporting systemic inflammation and cardiac changes provide support for the expanded body of epidemiologic evidence for

[19] For purposes of the exposure and risk estimates with adjusted air quality, the REA considered any value <76 ppb to be ''just meeting'' the current 75 ppb standard (U.S. EPA, 2014a).

[20] In previous reviews, including the 2008 review and reconsideration, such risks were separately estimated for O_3 concentrations characterized as above policy-relevant background concentrations. Policy-relevant background concentrations were defined as the distribution of O_3 concentrations attributable to sources other than anthropogenic emissions of O_3 precursor emissions (*e.g.,* VOC, CO, NO_X) in the U.S., Canada, and Mexico. The decision in this review to estimate total risk across the full range of O_3 concentrations reflects consideration of advice from CASAC (Frey and Samet, 2012b).

[21] In a series of sensitivity analyses, the HREA also evaluates a series of threshold models for respiratory mortality associated with long-term O_3 concentrations. The PA considers these risk estimates based on threshold models, in addition to HREA core estimates based on the linear model (U.S. EPA, 2014a, sections 3.2.3.2, 4.4.2.3).

[22] As noted below, for the 70 ppb exposure concentration, Schelegle et al. (2009) reported that the actual mean exposure concentration was 72 ppb.

[23] The consideration of ambient O_3 concentrations in the locations of these epidemiologic studies are discussed in sections II.D.1.b and II.E.4.a below, for the current standard and alternative standards, respectively.

cardiovascular mortality, although lack of coherence with epidemiologic studies of cardiovascular morbidity remains an important uncertainty.

(4) New epidemiologic studies provide expanded evidence for respiratory effects associated with long-term or repeated O_3 concentrations (*e.g.*, seasonal average of 1- or 8-hour daily max concentrations). Recent studies report interactions between exercise or different genetic variants and both new-onset asthma in children and increased respiratory symptom effects in individuals with asthma; additional studies of respiratory morbidity and mortality support the association between long-term exposure to O_3 and a range of respiratory health effects.

(5) New evidence of risk factors (*i.e.,* people with certain genetic variants related to antioxidant status or inflammation, and people with reduced intake of antioxidant nutrients) strengthens our understanding of the potential modes of action from O_3-induced effects.

1. Overview of Mechanisms

The purpose of this section is to describe the ISA's characterization of the key events and pathways that contribute to health effects resulting from both short-term and long-term exposures to O_3. The information in this section draws from section 5.3 of the ISA (U.S. EPA, 2013a). Mode of action refers to a sequence of key events and processes that result in a given toxic effect. Elucidation of mechanisms provides a more detailed understanding of these key events and processes. Experimental evidence elucidating modes of action and/or mechanisms contributes to our understanding of the biological plausibility of adverse O_3-related health effects, including respiratory effects and effects outside the respiratory system (U.S. EPA, 2013a, Chapters 6 and 7).

Figure 3.1 in the PA (U.S. EPA, 2014c) shows the current understanding of key events in the toxicity pathway of O_3, based on the available evidence. These key events are described briefly here and in more detail in section 3.1.1 of the PA. The initial key event is the formation of secondary oxidation products in the respiratory tract (U.S. EPA, 2013a, section 5.3). This mainly involves direct reactions with components of the extracellular lining fluid (ELF). Although the ELF has inherent capacity to quench (based on individual antioxidant capacity), this capacity can be overwhelmed, especially with exposure to elevated concentrations of O_3. The resulting secondary oxidation products transmit signals to the epithelium, pain receptive nerve fibers and, if present, immune cells (*i.e.,* eosinophils, dendritic cells and mast cells) involved in allergic responses. Thus, the available evidence indicates that the effects of O_3 are mediated by components of ELF and by the multiple cell types found in the respiratory tract. Further, oxidative stress is an implicit part of this initial key event.

It is well understood that secondary oxidation products initiate numerous responses at the cellular, tissue, and whole organ level of the respiratory system. These responses include the activation of neural reflexes leading to lung function decrements, airway obstruction, and extrapulmonary effects such as slow resting heart rate; initiation of inflammation; alteration of barrier epithelial function; sensitization of bronchial smooth muscle; modification of lung host defenses; and airways remodeling (U.S. EPA, 2013a, section 5.3.10, Figure 5–8). Each of these effects is discussed in more detail in section 3.1.1 of the PA (U.S. EPA, 2014c).

Persistent inflammation and injury, which are observed in animal models of chronic and intermittent exposure to O_3, are associated with airways remodeling (see Section 7.2.3 of the ISA, U.S. EPA 2013). Chronic intermittent exposure to O_3 has also been shown to result in effects on the developing lung and immune system. Systemic inflammation and vascular oxidative/nitrosative stress are also key events in the toxicity pathway of O_3. Extrapulmonary effects of O_3 occur in numerous organ systems, including the cardiovascular, central nervous, reproductive, and hepatic systems (U.S. EPA, 2013a, sections 6.3 to 6.5 and sections 7.3 to 7.5).

Responses to O_3 exposure are variable within the population. Studies have shown a large range of pulmonary function (*i.e.,* spirometric) responses to O_3 among healthy young adults, while responses within an individual are relatively consistent over time. Other responses to O_3 have also been characterized by a large degree of interindividual variability. For example, a 3- to 20-fold difference among subjects in their studies in airways inflammation (*i.e.,* neutrophilia influx) following O_3 exposure has been reported (Schelegle et al., 1991 and Devlin et al., 1991, respectively). Reproducibility of an individual's inflammatory response to O_3 exposure in humans, measured as sputum neutrophilia, was demonstrated by Holz et al (1999). Since individual inflammatory responses were relatively consistent across time, it was thought that inflammatory responsiveness reflected an intrinsic characteristic of the subject (Mudway and Kelly, 2000). While the basis for the observed interindividual variability in responsiveness to O_3 is not clear, section 5.4.2 of the ISA discusses mechanisms that may underlie the variability in responses seen among individuals. Certain functional genetic polymorphisms, pre-existing conditions or diseases, nutritional status, lifestages, and co-exposures contribute to altered risk of O_3-induced effects. Experimental evidence for such O_3-induced changes contributes to our understanding of the biological plausibility of adverse O_3-related health effects, including a range of respiratory effects as well as effects outside the respiratory system (*e.g.,* cardiovascular effects) (U.S. EPA, 2013a, Chapters 6 and 7).

2. Nature of Effects

The health effects of O_3 are described in detail and assessed in the ISA (U.S. EPA, 2013a). Based on this assessment, the ISA determined that a ''causal'' relationship exists between short-term exposure to O_3 in ambient air [24] and effects on the respiratory system and that a ''likely to be causal'' relationship [25] exists between long-term exposure to O_3 in ambient air and respiratory effects (U.S. EPA 2013a, pp. 1–6 to 1–7). As stated in the ISA, ''[c]ollectively, a very large amount of evidence spanning several decades supports a relationship between exposure to O_3 and a broad range of respiratory effects'' (US. EPA, 2013a, p. 1–6). The ISA summarizes the longstanding body of evidence for O_3 respiratory effects as follows (U.S. EPA, 2013a, p. 1–5):

> The clearest evidence for health effects associated with exposure to O_3 is provided by studies of respiratory effects. Collectively, a very large amount of evidence spanning several decades supports a relationship between exposure to O_3 and a broad range of respiratory effects (see Section 6.2.9 and Section 7.2.8). The majority of this evidence is derived from studies investigating short-term exposures (*i.e.,* hours to weeks) to O_3, although animal toxicological studies and recent epidemiologic evidence demonstrate that long-term exposure (*i.e.,* months to years) may also harm the respiratory system.

Additionally, the ISA determined that the relationships between short-term exposures to O_3 in ambient air and both total mortality and cardiovascular effects are likely to be causal, based on expanded evidence bases in the current review (U.S. EPA, 2013a, pp. 1–7 to 1–

[24] In determining that a causal relationship exists for O_3 with specific health effects, the EPA has concluded that ''[e]vidence is sufficient to conclude that there is a causal relationship with relevant pollutant exposures'' (U.S. EPA, 2013a, p. lxiv).

[25] In determining a ''likely to be a causal'' relationship exists for O_3 with specific health effects, the EPA has concluded that ''[e]vidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures, but important uncertainties remain'' (U.S. EPA, 2013a, p. lxiv).

8). In the ISA, the EPA additionally determined that the currently available evidence for additional endpoints is ''suggestive'' of causal relationships between short-term (central nervous system effects) and long-term exposure (cardiovascular effects, reproductive and developmental effects, central nervous system effects and total mortality) to ambient O_3.

Consistent with emphasis in past reviews on O_3 health effects for which the evidence is strongest, in this review the EPA places the greatest emphasis on studies of health effects that have been judged in the ISA to be caused by, or likely to be caused by, O_3 exposures (U.S. EPA, 2013a, section 2.5.2). This section discusses the evidence for health effects attributable to O_3 exposures, with a focus on respiratory morbidity and mortality effects attributable to short- and long-term exposures, and cardiovascular system effects (including mortality) and total mortality attributable to short-term exposures. This section focuses particularly on considering the extent to which the scientific evidence available in the current review has been strengthened since the last review, and the extent to which important uncertainties and limitations in the evidence from the last review have been addressed.

a. Respiratory Effects—Short-Term

The 2006 O_3 AQCD concluded that there was clear, consistent evidence of a causal relationship between short-term O_3 exposure and respiratory effects (U.S. EPA, 2006a). This conclusion was substantiated by evidence from controlled human exposure and toxicological studies indicating a range of respiratory effects in response to short-term O_3 exposures, including pulmonary function decrements and increases in respiratory symptoms, lung inflammation, lung permeability, and airway hyperresponsiveness. Toxicological studies provided additional evidence for O_3-induced impairment of host defenses. Combined, these findings from experimental studies provided support for epidemiologic evidence, in which short-term increases in ambient O_3 concentration were consistently associated with decreases in lung function in populations with increased outdoor exposures, especially children with asthma and healthy children; increases in respiratory symptoms and asthma medication use in children with asthma; and increases in respiratory-related hospital admissions and asthma-related emergency department visits (U.S. EPA, 2013a, pp. 6–1 to 6–2).

As discussed in detail in the ISA (U.S. EPA, 2013a, section 6.2.9), studies evaluated since the completion of the 2006 O_3 AQCD support and expand upon the strong body of evidence that, in the last review, indicated a causal relationship between short-term O_3 exposures and respiratory health effects. Recent controlled human exposure studies conducted in young, healthy adults with moderate exertion have reported forced expiratory volume in 1 second (FEV_1) decrements and pulmonary inflammation following prolonged exposures to O_3 concentrations as low as 60 ppb, and respiratory symptoms following exposures to concentrations as low as 72 ppb (based on group mean responses).[26] Epidemiologic studies provide evidence that increases in ambient O_3 exposures are associated with lung function decrements, increases in respiratory symptoms, and pulmonary inflammation in children with asthma; increases in respiratory-related hospital admissions and emergency department visits; and increases in respiratory mortality. Some of these studies report such associations even for O_3 concentrations at the low end of the distribution of daily concentrations. Recent epidemiologic studies report that associations with respiratory morbidity and mortality are stronger during the warm/summer months and remain robust after adjustment for copollutants. Recent toxicological studies reporting O_3-induced inflammation, airway hyperresponsiveness, and impaired lung host defense continue to support the biological plausibility and modes of action for the O_3-induced respiratory effects observed in the controlled human exposure and epidemiologic studies. Further support is provided by recent studies that found O_3-associated increases in indicators of airway inflammation and oxidative stress in children with asthma (U.S. EPA, 2013a, section 6.2.9). Together, epidemiologic and experimental studies support a continuum of respiratory effects associated with O_3 exposure that can result in respiratory-related emergency department visits, hospital admissions, and/or mortality (U.S. EPA, 2013a, section 6.2.9).

Across respiratory endpoints, evidence indicates antioxidant capacity may modify the risk of respiratory morbidity associated with O_3 exposure (U.S. EPA, 2013a, section 6.2.9, p. 6–161). The potentially elevated risk of populations with diminished antioxidant capacity and the reduced risk of populations with sufficient antioxidant capacity is supported by epidemiologic studies and from controlled human exposure studies. Additional evidence characterizes O_3-induced decreases in antioxidant levels as a key event in the mode of action for downstream effects.

Key aspects of this evidence are discussed below with regard to lung function decrements; pulmonary inflammation, injury, and oxidative stress; airway hyperresponsiveness; respiratory symptoms and medication use; lung host defense; allergic and asthma-related responses; hospital admissions and emergency department visits; and respiratory mortality.[27]

i. Lung Function Decrements

In the 2008 review, a large number of controlled human exposure studies[28] reported O_3-induced lung function decrements in young, healthy adults engaged in intermittent, moderate exertion following 6.6 hour exposures to O_3 concentrations at or above 80 ppb. Although two studies also reported effects following exposures to lower concentrations, an important uncertainty in the last review was the extent to which exposures to O_3 concentrations below 80 ppb result in lung function decrements. In addition, in the last review epidemiologic panel studies had reported O_3-associated lung function decrements in a variety of different populations (*e.g.,* children, outdoor workers) likely to experience increased exposures. In the current review, additional controlled human exposure studies are available that have evaluated exposures to O_3 concentrations of 60 or 72 ppb. The available evidence from controlled human exposure and panel studies is

[26] Schelegle et al. (2009) reported a statistically significant increase in respiratory symptoms in healthy adults at a target O_3 exposure concentration of 70 ppb, averaged over the study period. For this 70 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual mean exposure concentration was 72 ppb.

[27] CASAC concurred that these were ''the kinds of identifiable effects on public health that are expected from the presence of ozone in the ambient air'' (Frey 2014c, p. 3).

[28] The controlled human exposure studies emphasized in the PA utilize only healthy adult subjects. In the near absence of controlled human exposure data for children, HREA estimates of lung function decrements are based on the assumption that children exhibit the same lung function responses following O_3 exposures as healthy 18 year olds (U.S. EPA, 2014a, section 6.2.4 and 6.5). This assumption is justified in part by the findings of McDonnell et al. (1985), who reported that children (8–11 years old) experienced FEV_1 responses similar to those observed in adults (18–35 years old). Thus, the conclusions about the occurrence of lung function decrements that follow generally apply to children as well as to adults.

assessed in detail in the ISA (U.S. EPA, section 6.2.1) and is summarized below.

Controlled exposures to O_3 concentrations that can be found in the ambient air can result in a number of lung function effects, including decreased inspiratory capacity, mild bronchoconstriction, and rapid, shallow breathing patterns during exercise. Reflex inhibition of inspiration results in a decrease in forced vital capacity (FVC) and total lung capacity (TLC) and, in combination with mild bronchoconstriction, contributes to a decrease in FEV_1 (U.S. EPA, 2013a, section 6.2.1.1). Accumulating evidence indicates that such effects are mediated by activation of sensory nerves, resulting in the involuntary truncation of inspiration and a mild increase in airway obstruction due to bronchoconstriction (U.S. EPA, 2013a, section 5.3.10).

Data from controlled human exposure studies show that increasing the duration of O_3 exposures and increasing ventilation rates decreases the O_3 exposure concentrations required to impair lung function. Ozone exposure concentrations well above those typically found in ambient air are required to impair lung function in healthy resting adults, while exposure to O_3 concentrations at or below those in the ambient air have been reported to impair lung function in healthy adults exposed for longer durations while undergoing intermittent, moderate exertion (U.S. EPA, 2013a, section 6.2.1.1). With repeated O_3 exposures over several days, FEV_1 responses become attenuated in both healthy adults and adults with mild asthma, though this attenuation of response is lost after about a week without exposure (U.S. EPA, 2013a, section 6.2.1.1; p. 6–27).

When considering controlled human exposure studies of O_3-induced lung function decrements, the ISA and PA evaluate both group mean changes in lung function and the interindividual variability in the magnitude of responses. An advantage of O_3 controlled human exposure studies (*i.e.*, compared to the epidemiologic panel studies discussed below) is that reported effects necessarily result from exposures to O_3 itself.[29] To the extent studies report statistically significant decrements in mean lung function following O_3 exposures after controlling for other factors, these studies provide greater confidence that measured decrements are due to the O_3 exposure itself, rather than to chance alone. As discussed below, group mean changes in lung function are often small, especially following exposures to relatively low O_3 concentrations (*e.g.*, 60 ppb). However, even when group mean decrements in lung function are small, some individuals could experience decrements that are ''clinically meaningful'' (Pellegrino et al., 2005; ATS, 1991) with respect to criteria for spirometric testing, and/or that could be considered adverse with respect to public health policy decisions (see section II.B.3, below).

At the time of the last review, a number of controlled human exposure studies had reported lung function decrements in young, healthy adults following prolonged (6.6-hour) exposures while at moderate exertion to O_3 concentrations at and above 80 ppb. In addition, there were two controlled human exposure studies by Adams (2002, 2006) that examined lung function effects following exposures to 60 ppb O_3. The EPA's analysis of the data from the Adams (2006) study reported a small but statistically significant O_3-induced decrement in group mean FEV_1 following exposures of young, healthy adults to 60 ppb O_3 while at moderate exertion, when compared with filtered air controls (Brown et al., 2008).[30] Further examination of the post-exposure FEV_1 data, and mean data for other time points and other concentrations, indicated that the temporal pattern of the response to 60 ppb O_3 was generally consistent with the temporal patterns of responses to higher O_3 concentrations in this and other studies (75 FR 2950, January 19, 2010). This suggested a pattern of response following exposures to 60 ppb O_3 that was consistent with a dose-response relationship, rather than random variability. See also *State of Mississippi* v. *EPA*, F. 3d at 1347 (upholding EPA's interpretation of the Adams studies).

Figure 6–1 in the ISA summarizes the currently available evidence from multiple controlled human exposure studies evaluating group mean changes in FEV_1 following prolonged O_3 exposures (*i.e.*, 6.6 hours) in young, healthy adults engaged in moderate levels of physical activity (U.S. EPA, 2013a, section 6.2.1.1). With regard to the group mean changes reported in these studies, the ISA specifically notes the following (U.S. EPA, 2013a, section 6.2.1.1, Figure 6–1):

1. Prolonged exposure to 40 ppb O_3 results in a small decrease in group mean FEV_1 that is not statistically different from responses following exposure to filtered air (Adams, 2002; Adams, 2006).

2. Prolonged exposure to an average O_3 concentration of 60 ppb results in group mean FEV_1 decrements ranging from 1.8% to 3.6% (Adams 2002; Adams, 2006;[31] Schelegle et al., 2009;[32] Kim et al., 2011). Based on data from multiple studies, the weighted average group mean decrement was 2.7%. In some analyses, these group mean decrements in lung function were statistically significant (Brown et al., 2008; Kim et al., 2011), while in other analyses they were not (Adams, 2006; Schelegle et al., 2009).[33]

3. Prolonged exposure to an average O_3 concentration of 72 ppb results in a statistically significant group mean decrement in FEV_1 of about 6% (Schelegle et al., 2009).[34]

4. Prolonged square-wave exposure to average O_3 concentrations of 80 ppb, 100 ppb, or 120 ppb O_3 results in statistically significant group mean decrements in FEV_1 ranging from 6 to 8%, 8 to 14%, and 13 to 16%, respectively (Folinsbee et al., 1988; Horstman et al., 1990; McDonnell et al., 1991; Adams, 2002; Adams, 2003; Adams, 2006).

As illustrated in Figure 6–1 of the ISA, there is a smooth dose-response

[29] The ISA notes that the use of filtered air responses as a control for the assessment of responses following O_3 exposure in controlled human exposure studies serves to eliminate alternative explanations other than O_3 itself in causing the measured responses (U.S. EPA, 2013a, section 6.2.1.1).

[30] Adams (2006) did not find effects on FEV_1 at 60 ppb to be statistically significant. In an analysis of the Adams (2006) data, Brown et al. (2008) showed that even after removal of potential outliers, the average effect on FEV_1 at 60 ppb was small, but highly statistically significant ($p < 0.002$) using several common statistical tests.

[31] Adams (2006); (2002) both provide data for an additional group of 30 healthy subjects that were exposed via facemask to 60 ppb (square-wave) O_3 for 6.6 hours with moderate exercise ($\dot{V}_E$ = 23 L/min per m^2 BSA). These subjects are described on page 133 of Adams (2006) and pages 747 and 761 of Adams (2002). The FEV_1 decrement may be somewhat increased due to a target $\dot{V}_E$ of 23 L/min per m^2 BSA relative to other studies having the target $\dot{V}_E$ of 20 L/min per m^2 BSA. The facemask exposure is not expected to affect the FEV_1 responses relative to a chamber exposure.

[32] For the 60 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual mean exposure concentration was 63 ppb.

[33] Adams (2006) did not find effects on FEV_1 at 60 ppb to be statistically significant. In an analysis of the Adams (2006) data, Brown et al. (2008) addressed the more fundamental question of whether there were statistically significant differences in responses before and after the 6.6 hour exposure period and found the average effect on FEV_1 at 60 ppb to be small, but highly statistically significant using several common statistical tests, even after removal of potential outliers. Schelegle et al. (2009) reported that, compared to filtered air, the largest change in FEV_1 for the 60 ppb protocol occurred after the sixth (and final) exercise period.

[34] As noted above, for the 70 ppb exposure group, Schelegle et al. (2009) reported that the actual mean exposure concentration was 72 ppb.

curve without evidence of a threshold for exposures between 40 and 120 ppb O_3 (U.S. EPA, 2013a, Figure 6–1). When these data are taken together, the ISA concludes that ''mean FEV_1 is clearly decreased by 6.6-hour exposures to 60 ppb O_3 and higher concentrations in [healthy, young adult] subjects performing moderate exercise'' (U.S. EPA, 2013a, p. 6–9).

With respect to interindividual variability in lung function, in an individual with relatively ''normal'' lung function, with recognition of the technical and biological variability in measurements, within-day changes in FEV_1 of ≥5% are clinically meaningful (Pellegrino et al., 2005; ATS, 1991). The ISA (U.S. EPA, 2013a, section 6.1.) focuses on individuals with >10% decrements in FEV_1 for two reasons. A 10% FEV_1 decrement is accepted by the American Thoracic Society (ATS) as an abnormal response and a reasonable criterion for assessing exercise-induced bronchoconstriction (Dryden et al., 2010; ATS, 2000). (U.S. EPA, 2013a, section 6.2.1.1). Also, some individuals in the Schelegle et al. (2009) study experienced 5–10% FEV_1 decrements following exposure to filtered air.

In previous NAAQS reviews, the EPA has made judgments regarding the potential implications for individuals experiencing FEV_1 decrements of varying degrees of severity.[35] For people with lung disease, the EPA judged that moderate functional decrements (*e.g.,* FEV_1 decrements >10% but <20%, lasting up to 24 hours) would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication (75 FR 2973, January 19, 2010). In previous reviews CASAC has endorsed these conclusions. In the context of standard setting, in the last review of the O_3 NAAQS CASAC indicated that it is appropriate to focus on the lower end of the range of moderate functional responses (*e.g.,* FEV_1 decrements ≥10%) when estimating potentially adverse lung function decrements in people with lung disease, especially children with asthma (Henderson, 2006c; transcript of CASAC meeting, day 8/24/06, page 149). More specifically, CASAC stated that ''[a] 10% decrement in FEV_1 can lead to respiratory symptoms, especially in individuals with pre-existing pulmonary or cardiac disease. For example, people with chronic obstructive pulmonary disease have decreased ventilatory reserve (*i.e.,* decreased baseline FEV_1) such that a ≥10% decrement could lead to moderate to severe respiratory symptoms'' (Samet, 2011). In this review, CASAC reiterated its support for this conclusion, stating that ''[a]n FEV1 decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease'' (Frey, 2014c p. 3). Therefore, in considering interindividual variability in O_3-induced lung function decrements in the current review, the EPA also focuses on the extent to which individuals were reported to experience FEV_1 decrements of 10% or greater.[36]

New studies (Schelegle et al., 2009; Kim et al., 2011) add to the previously available evidence for interindividual variability in the responses of healthy adults following exposures to O_3. Following prolonged exposures to 80 ppb O_3 while at moderate exertion, the proportion of healthy adults experiencing FEV_1 decrements greater than 10% was 17% by Adams (2006), 26% by McDonnell (1996), and 29% by Schelegle et al. (2009). Following exposures to 60 ppb O_3, that proportion was 20% by Adams (2002), 3% by Adams (2006), 16% by Schelegle et al. (2009), and 5% by Kim et al. (2011). Across these studies, the weighted average proportion (*i.e.,* based on numbers of subjects in each study) of young, healthy adults with >10% FEV_1 decrements is 25% following exposure to 80 ppb O_3 and 10% following exposure to 60 ppb O_3, for 6.6 hours at moderate exertion (U.S. EPA, 2013a, page 6–18 and 6–19).[37] [38] The ISA notes that responses within an individual tend to be reproducible over a period of several months, indicating that interindividual differences reflect differences in intrinsic responsiveness. Given this, the ISA concludes that ''[t]hough group mean decrements are biologically small and generally do not attain statistical significance, a considerable fraction of exposed individuals experience clinically meaningful decrements in lung function'' when exposed for 6.6 hours to 60 ppb O_3 during quasi continuous, moderate exertion (U.S. EPA, 2013a, section 6.2.1.1, p. 6–20).

This review has marked an advance in the ability to make reliable quantitative predictions of the potential lung function response to ozone exposure, and thus to reasonably predict the degree of interindividual response of lung function to that exposure. McDonnell et al. (2012) and Schelegle et al. (2012) developed models using data on O_3 exposure concentrations, ventilation rates, duration of exposures, and lung function responses from a number of controlled human exposure studies. See section 6.2.1.1 of the ISA (U.S. EPA 2013a, p. 6–15). The McDonnell et al. (2012) and Schelegle et al. (2012) studies analyzed large datasets to fit compartmental models that included the concept of a dose of onset in lung function response or a response threshold based upon the inhaled O_3 dose. The McDonnell et al. (2012) model was fit to a dataset consisting of the FEV_1 responses of 741 young, healthy adults (18–35 years of age) from 23 individual controlled exposure studies. Concentrations across individual studies ranged from 40 ppb to 400 ppb,[39] activity level ranged from rest to heavy exercise, duration of exposure was from 2 to 7.6 hours. The extension of the McDonnell et al. (2012) model to children and older adults is discussed in section 6.2.4 of the HREA (U.S. EPA, 2014a). Schelegle et al. (2012) also analyzed a large dataset with substantial overlap to that used by McDonnell et al. (2012). The Schelegle et al. (2012) model was fit to the FEV_1 responses of 220 young healthy adults (taken from a dataset of 704 individuals) from 21 individual controlled exposure studies. The resulting empirical models can estimate the frequency distribution of individual responses for any exposure scenario as well as summary measures of the distribution such as the mean or median response and the proportions of individuals with FEV_1 decrements >10%, 15%, and 20%.

The predictions of the McDonnell and Schelegle models are consistent with the observed results from the individual studies of O_3-induced FEV_1 decrements. Specifically, McDonnell et al. (2012) estimated that 9% of healthy exercising adults would experience FEV_1 decrements greater than 10% following

[35] Such judgments have been made for decrements in FEV_1 as well as for increased airway responsiveness and symptomatic responses (*e.g.,* cough, chest pain, wheeze). Ranges of pulmonary responses and their associated potential impacts are presented in Tables 3–2 and 3–3 of the 2007 Staff Paper (U.S. EPA, 2007).

[36] The approach to using results from controlled human exposure studies conducted in healthy adults to provide perspective on the potential public health impacts of O_3-related respiratory health effects is discussed in section II.A above, and in sections II.C.2 and II.C.3 below.

[37] The ISA notes that by considering responses uncorrected for filtered air exposures, during which lung function typically improves (which would increase the size of the change, pre-and post-exposure), 10% is an underestimate of the proportion of healthy individuals that are likely to experience clinically meaningful changes in lung function following exposure for 6.6 hours to 60 ppb O_3 during intermittent moderate exertion (U.S. EPA, 2012, section 6.2.1.1).

[38] Based on the data available at 60 ppb, 1% of subjects experienced decrements >20% (also uncorrected for filtered air exposures).

[39] Responses to O_3 in these studies were adjusted for responses observed following exposure to filtered air.

6.6 hour exposure to 60 ppb O_3, and that 22% would experience such decrements following exposure to 80 ppb O_3 (U.S. EPA, 2013a, p. 6–18 and Figure 6–3).[40] Schelegle et al. (2012) estimated that, for a prolonged (6.6 hours) O_3 exposure with moderate, quasi-continuous exercise, the average dose of onset for FEV_1 decrement would be reached following 4 to 5 hours of exposure to 60 ppb, and following 3 to 4 hours of exposure to 80 ppb. However, 14% of the individuals were estimated to have a dose of onset that was less than 40% of the average. Those individuals were estimated to reach their dose of onset following 1 to 2 hours of exposure to 50 to 80 ppb O_3 (U.S. EPA, 2013a, p. 6–16), which is consistent with the threshold FEV_1 responses reported by McDonnell et al. (2012).

CASAC agreed that these models mark a significant technical advance over the exposure-response modeling approach used in the last review (Frey, 2014a), stating that ''the comparison of the MSS [McDonnell-Stewart-Smith] model results to those obtained with the exposure-response (E–R) model is of tremendous importance. Typically, the MSS model gives results about a factor of three higher than the E–R model for school-aged children, which is expected because the MSS model includes responses for a wider range of exposure protocols (under different levels of exertion, lengths of exposure, and patterns of exposure concentrations) than the E–R model'' (Frey, 2014a, p. 7). CASAC explicitly found ''the updated and expanded lung finds the MSS model to be scientifically and biologically defensible.'' (Frey, 2014a, pp. 2, 8).

As discussed above and in the ISA (U.S EPA, 2013a, Section 5.3.2), secondary oxidation products formed following O_3 exposures can activate neural reflexes leading to decreased lung function. The McDonnell and Schelegle models included mathematical approaches to simulate the potential protective effect of antioxidants in the ELF at lower ambient O_3 concentrations, and include a dose threshold below which changes in lung function do not occur.

Epidemiologic studies[41] have consistently linked short-term increases in ambient O_3 concentrations with lung function decrements in diverse populations and lifestages, including children attending summer camps, adults exercising or working outdoors, and groups with pre-existing respiratory diseases such as asthmatic children (U.S. EPA, 2013a, section 6.2.1.2). Some of these studies reported O_3-associated lung function decrements accompanied by respiratory symptoms[42] in asthmatic children (Just et al., 2002; Mortimer et al., 2002; Ross et al., 2002; Gielen et al., 1997; Romieu et al., 1997; Thurston et al., 1997; Romieu et al., 1996). In contrast, studies of children in the general population have reported similar O_3-associated lung function decrements but without accompanying respiratory symptoms (Ward et al., 2002; Gold et al., 1999; Linn et al., 1996) (U.S. EPA, 2013a, section 6.2.1.2).

Several epidemiologic panel studies[43] reported statistically significant associations with lung function decrements at relatively low ambient O_3 concentrations. For outdoor recreation or exercise, associations were reported in analyses restricted to 1-hour average O_3 concentrations less than 80 ppb (Spektor et al., 1988a; Spektor et al., 1988b), 60 ppb (Brunekreef et al., 1994; Spektor et al., 1988a), and 50 ppb (Brunekreef et al., 1994). Among outdoor workers, Brauer et al. (1996) found a robust association with daily 1-hour max O_3 concentrations less than 40 ppb. Ulmer et al. (1997) found a robust association in schoolchildren with 30-minute maximum O_3 concentrations less than 60 ppb. For 8-hour average O_3 concentrations, associations with lung function decrements in children with asthma were found to persist at concentrations less than 80 ppb in a U.S. multicity study (Mortimer et al., 2002) and less than 51 ppb in a study conducted in the Netherlands (Gielen et al., 1997).

Epidemiologic panel studies investigating the effects of short-term exposure to O_3 provided information on potential confounding by copollutants such as particulate matter with a median aerodynamic diameter less than or equal to 2.5 microns ($PM_{2.5}$), particulate matter with a median aerodynamic diameter less than or equal to 10 microns (PM_{10}), nitrogen dioxide (NO_2), or sulfur dioxide (SO_2). These studies varied in how they evaluated confounding. Some studies of subjects exercising outdoors indicated that ambient concentrations of copollutants such as NO_2, SO_2, or acid aerosol were low, and thus not likely to confound associations observed for O_3 (Hoppe et al., 2003; Brunekreef et al., 1994; Hoek et al., 1993). In other studies of children with increased outdoor exposures, O_3 was consistently associated with decreases in lung function, whereas other pollutants such as $PM_{2.5}$, sulfate, and acid aerosol individually showed variable associations across studies (Thurston et al., 1997; Castillejos et al., 1995; Berry et al., 1991; Avol et al., 1990; Spektor et al., 1988a). Studies that conducted copollutant modeling generally found O_3-associated lung function decrements to be robust (*i.e.,* most copollutant-adjusted effect estimates fell within the 95% confidence interval (CI) of the single-pollutant effect estimates) (U.S. EPA, 2013a, Figure 6–10 and Table 6–14). Most O_3 effect estimates for lung function were robust to adjustment for temperature, humidity, and copollutants such as $PM_{2.5}$, PM_{10}, NO_2, or SO_2. Although examined in only a few epidemiologic studies, O_3 also remained associated with decreases in lung function with adjustment for pollen or acid aerosols (U.S. EPA, 2013a, section 6.2.1.2).

Several epidemiologic studies demonstrated the protective effects of vitamin E and vitamin C supplementation, and increased dietary antioxidant intake, on O_3-induced lung function decrements (Romieu et al., 2002) (U.S. EPA, 2013a, Figure 6–7 and Table 6–8).[44] These results provide support for the new, quantitative models (McDonnell et al., 2012; Schelegle et al., 2012), discussed above, which make use of the concept of oxidant stress to estimate the occurrence of lung function decrements following exposures to relatively low O_3 concentrations.

In conclusion, new information from controlled human exposure studies considerably strengthens the evidence and reduces the uncertainties, relative to the evidence that was available at the time of the 2008 review, regarding the presence and magnitude of lung function decrements in healthy adults following prolonged exposures to O_3 concentrations below 80 ppb. As discussed in Section 6.2.1.1 in the ISA (U.S. EPA, 2013, p. 6–12), there is information available from four separate studies that evaluated exposures to 60 ppb O_3 (Kim et al., 2011; Schelegle et al., 2009; Adams 2002; 2006). Although not consistently statistically significant, group mean FEV_1 decrements following exposures to 60 ppb O_3 are consistent

[40] Also consistent with the data from published studies (see above), this model predicts that 1% of people would experience FEV_1 decrements >20% following 6.6 hour exposure to 60 ppb O_3.

[41] Unless otherwise specified, the epidemiologic studies discussed in the PA evaluate only adults.

[42] Reversible loss of lung function in combination with the presence of symptoms meets the ATS definition of adversity (ATS, 2000).

[43] Panel studies include repeated measurements of health outcomes, such as respiratory symptoms, at the individual level (U.S. EPA, 2013a, p. 1x).

[44] Evidence from controlled human exposure studies is mixed, suggesting that supplementation may be ineffective in the absence of antioxidant deficiency (U.S. EPA, 2013a, p. 5–63).

among these studies. Moreover, as is illustrated in Figure 6–1 of the ISA (U.S. EPA, 2013a), the group mean FEV_1 responses at 60 ppb fall on a smooth intake dose-response curve for exposures between 40 and 120 ppb O_3. Based on the data in these studies, 10% of young, healthy adults experience clinically meaningful decrements in lung function when exposed for 6.6 hours to 60 ppb O_3 during intermittent, moderate exertion. One recent study has also reported statistically significant decrements following exposures to 72 ppb O_3 (Schelegle et al., 2009). Predictions from newly developed quantitative models are consistent with these experimental results. Additionally, as discussed in more detail in section II.B.4 below, epidemiologic studies continue to provide evidence of lung function decrements in people who are active outdoors, including people engaged in outdoor recreation or exercise, children, and outdoor workers, at low ambient O_3 concentrations. While few new epidemiologic studies of O_3-associated lung function decrements are available in this review, previously available studies have reported associations with decrements, including at relatively low ambient O_3 concentrations.

ii. Pulmonary Inflammation, Injury, and Oxidative Stress

Ozone exposures result in increased respiratory tract inflammation and epithelial permeability. Inflammation is a host response to injury, and the induction of inflammation is evidence that injury has occurred. Oxidative stress has been shown to play a key role in initiating and sustaining O_3-induced inflammation. Secondary oxidation products formed as a result of reactions between O_3 and components of the ELF can increase the expression of molecules (*i.e.,* cytokines, chemokines, and adhesion molecules) that can enhance airway epithelium permeability (U.S. EPA, 2013a, sections 5.3.3 and 5.3.4). As discussed in detail in the ISA (U.S. EPA, 2013a, section 6.2.3), O_3 exposures can initiate an acute inflammatory response throughout the respiratory tract that has been reported to persist for at least 18–24 hours after exposure.

Inflammation induced by exposure of humans to O_3 can have several potential outcomes: (1) Inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely; (2) continued acute inflammation can evolve into a chronic inflammatory state; (3) continued inflammation can alter the structure and function of other pulmonary tissue, leading to diseases such as asthma; (4) inflammation can alter the body's host defense response to inhaled microorganisms, particularly in potentially at-risk populations or lifestages such as the very young and old; and (5) inflammation can alter the lung's response to other agents such as allergens or toxins (U.S. EPA, 2013a, section 6.2.3). Thus, lung injury and the resulting inflammation provide a mechanism by which O_3 may cause other more serious morbidity effects (*e.g.,* asthma exacerbations).[45]

In the last review, controlled human exposure studies reported O_3-induced airway inflammation following exposures at or above 80 ppb and animal toxicological studies provided evidence for increases in inflammation and permeability in rabbits at levels as low as 100 ppb O_3. In the current review, the link between O_3 exposures and airway inflammation and injury has been evaluated in additional controlled human exposure studies, as well as in recent epidemiologic studies. Controlled human exposure studies have generally been conducted in young, healthy adults or in adults with asthma using lavage (proximal airway and bronchoalveolar), bronchial biopsy, and more recently, induced sputum. These studies have evaluated one or more indicators of inflammation, including neutrophil[46] (PMN) influx, markers of eosinophilic inflammation, increased permeability of the respiratory epithelium, and/or prevalence of proinflammatory molecules (U.S. EPA, 2013a, section 6.2.3.1). Epidemiologic studies have generally evaluated associations between ambient O_3 and markers of inflammation and/or oxidative stress, which plays a key role in initiating and sustaining inflammation (U.S. EPA, 2013a, section 6.2.3.2).

There is an extensive body of evidence from controlled human exposure studies indicating that short-term exposures to O_3 can cause pulmonary inflammation. A single acute exposure (1–4 hours) of humans to moderate concentrations of O_3 (200–600 ppb) while exercising at moderate to heavy intensities resulted in a number of cellular and biochemical changes in the lung, including inflammation characterized by increased numbers of PMNs, increased permeability of the epithelial lining of the respiratory tract, cell damage, and production of proinflammatory molecules (*i.e.,* cytokines and prostaglandins, U.S. EPA, 2006a). A meta-analysis of 21 controlled human exposure studies (Mudway and Kelly, 2004) using varied experimental protocols (80–600 ppb O_3 exposures; 1–6.6 hours exposure duration; light to heavy exercise; bronchoscopy at 0–24 hours post-O_3 exposure) reported that PMN influx in healthy subjects is linearly associated with total O_3 dose.

Several studies, including one published since the last review (Alexis et al., 2010), have reported O_3-induced increases in PMN influx and permeability following exposures at or above 80 ppb (Alexis et al., 2010; Peden et al., 1997; Devlin et al., 1991), and eosinophilic inflammation following exposures at or above 160 ppb (Scannell et al., 1996; Peden et al., 1997; Hiltermann et al., 1999; Vagaggini et al., 2002). In addition, one recent controlled human exposure study has reported O_3-induced PMN influx following exposures of healthy adults to 60 ppb O_3 (Kim et al., 2011), the lowest concentration at which inflammatory responses have been evaluated in human studies.

As with FEV_1 responses to O_3, inflammatory responses to O_3 are generally reproducible within individuals, with some individuals experiencing more severe O_3-induced airway inflammation than indicated by group averages (Holz et al., 2005; Holz et al., 1999). Unlike O_3-induced decrements in lung function, which are attenuated following repeated exposures over several days (U.S. EPA, 2013a, section 6.2.1.1), some markers of O_3-induced inflammation and tissue damage remain elevated during repeated exposures, indicating ongoing damage to the respiratory system (U.S. EPA, 2013a, section 6.2.3.1).

Most controlled human exposure studies have reported that asthmatics experience larger O_3-induced inflammatory responses than non-asthmatics.[47] Specifically, asthmatics

[45] CASAC also addressed this issue: ''The CASAC believes that these modest changes in FEV_1 are usually associated with inflammatory changes, such as more neutrophils in the bronchoalveolar lavage fluid. Such changes may be linked to the pathogenesis of chronic lung disease'' (Frey, 2014a p. 2).

[46] Referred to as either neutrophils or polymorphonuclear neutrophils (or PMNs), these are the most abundant type of white blood cells in mammals. PMNs are recruited to the site of injury following trauma and are the hallmark of acute inflammation. The presence of PMNs in the lung has long been accepted as a hallmark of inflammation and is an important indicator that O_3 causes inflammation in the lungs. Neutrophilic inflammation of tissues indicates activation of the innate immune system and requires a complex series of events, that then are normally followed by processes that clear the evidence of acute inflammation.

[47] When evaluated, these studies have also reported O_3-induced respiratory symptoms in asthmatics. Specifically, Scannell et al. (1996), Basha et al. (1994), and Vagaggini et al. (2001, 2007)

exposed to 200 ppb O_3 for 4–6 hours with exercise show significantly more neutrophils in bronchoalveolar lavage fluid (BALF) than similarly exposed healthy individuals (Scannell et al., 1996; Basha et al., 1994). Bosson et al. (2003) reported significantly greater expression of a variety of pro-inflammatory cytokines in asthmatics, compared to healthy subjects, following exposure to 200 ppb O_3 for 2 hours. In addition, research available in the last review, combined with a recent study newly available in this review, indicates that pretreatment of asthmatics with corticosteroids can prevent the O_3-induced inflammatory response in induced sputum, though pretreatment did not prevent FEV_1 decrements (Vagaggini et al., 2001; 2007). In contrast, Stenfors et al. (2002) did not detect a difference in the O_3-induced increases in neutrophil numbers between 15 subjects with mild asthma and 15 healthy subjects by bronchial wash at the 6 hours postexposure time point, although the neutrophil increase in the asthmatic group was on top of an elevated baseline.

In people with allergic airway disease, including people with rhinitis and asthma, evidence available in the last review indicated that proinflammatory mediators also cause accumulation of eosinophils in the airways (Jorres et al., 1996; Peden et al., 1995 and 1997; Frampton et al., 1997; Hiltermann et al., 1999; Holz et al., 2002; Vagaggini et al., 2002). The eosinophil, which increases inflammation and allergic responses, is the cell most frequently associated with exacerbations of asthma (72 FR 37846, July 11, 2007).

Studies reporting inflammatory responses and markers of lung injury have clearly demonstrated that there is important variation in the responses of exposed subjects (72 FR 37831, July 11, 2007). Some individuals also appear to be intrinsically more susceptible to increased inflammatory responses from O_3 exposure (Holz et al., 2005). In healthy adults exposed to each 80 and 100 ppb O_3, Devlin et al. (1991) observed group average increases in neutrophilic inflammation of 2.1- and 3.8-fold, respectively. However, there was a 20-fold range in inflammatory responses between individuals at both concentrations. Relative to an earlier, similar study conducted at 400 ppb (Koren et al., 1989), Devlin et al. (1991) noted that although some of the study population showed little or no increase in inflammatory and cellular injury indicators analyzed after exposures to lower levels of O_3 (*i.e.,* 80 and 100 ppb), others had changes that were as large as those seen when subjects were exposed to 400 ppb O_3. The study authors concluded that, ''while the population as a whole may have a small inflammatory response to near-ambient levels of ozone, there may be a significant subpopulation that is very sensitive to these low levels'' (Devlin et al., 1991).

A number of studies report that O_3 exposures increase epithelial permeability. Increased BALF protein, suggesting O_3-induced changes in epithelial permeability, has been reported at 1 hour and 18 hours postexposure (Devlin et al., 1997; Balmes et al., 1996). A meta-analysis of results from 21 publications (Mudway and Kelly, 2004) for varied experimental protocols (80–600 ppb O_3; 1–6.6 hours duration; light to heavy exercise; bronchoscopy at 0–24 hours post-O_3 exposure; healthy subjects), showed that increased BALF protein is associated with total inhaled O_3 dose. As noted in the 2009 PM ISA (U.S. EPA, 2009a), it has been postulated that changes in permeability associated with acute inflammation may provide increased access of inhaled antigens, particles, and other inhaled substances deposited on lung surfaces to the smooth muscle, interstitial cells, immune cells underlying the epithelium, and the blood (U.S. EPA, 2013a, sections 5.3.4, 5.3.5). As has been observed with FEV_1 responses, within individual changes in permeability are correlated with changes following sequential O_3 exposures (Que et al., 2011). Changes in permeability and AHR apear to be mediated by different pathways. Animal toxicology studies have provided some support for this hypothesis (Adamson and Prieditis, 1995; Chen et al., 2006), though these studies did not specifically evaluate O_3 exposures (U.S. EPA, 2009a).

The limited epidemiologic evidence reviewed in the 2006 O_3 AQCD (U.S. EPA, 2006a) reported associations between short-term increases in ambient O_3 concentrations and airways inflammation in children (1-hour max O_3 of approximately 100 ppb). In the 2006 O_3 AQCD (U.S. EPA, 2006a), there was limited evidence for increases in nasal lavage levels of inflammatory cell counts and molecules released by inflammatory cells (*i.e.,* eosinophilic cationic protein, and myeloperoxidases). Since 2006, as a result of the development of less invasive methods, there has been a large increase in the number of studies assessing ambient O_3-associated changes in airway inflammation and oxidative stress, the types of biological samples collected, and the types of indicators. Most of these recent studies have evaluated biomarkers of inflammation or oxidative stress in exhaled breath, nasal lavage fluid, or induced sputum (U.S. EPA, 2013a, section 6.2.3.2). These recent studies form a larger database to establish coherence with findings from controlled human exposure and animal studies that have measured the same or related biological markers. Additionally, results from these studies provide further biological plausibility for the associations observed between ambient O_3 concentrations and respiratory symptoms and asthma exacerbations.

A number of epidemiologic studies provide evidence that short-term increases in ambient O_3 exposure increase pulmonary inflammation and oxidative stress in children, including those with asthma (Sienra-Monge et al., 2004; Barraza-Villarreal et al., 2008; Romieu et al., 2008; Berhane et al., 2011). Multiple studies examined and found increases in exhaled nitric oxide (eNO)[48] (Berhane et al., 2011; Khatri et al., 2009; Barraza-Villarreal et al., 2008). In some studies of subjects with asthma, increases in ambient O_3 concentration at the same lag were associated with both increases in pulmonary inflammation and respiratory symptoms (Khatri et al., 2009; Barraza-Villarreal et al., 2008). Although more limited in number, epidemiologic studies also found associations with cytokines such as IL–6 or IL–8 (Barraza-Villarreal et al., 2008; Sienra-Monge et al., 2004), eosinophils (Khatri et al., 2009), antioxidants (Sienra-Monge et al., 2004), and indicators of oxidative stress (Romieu et al., 2008) (U.S. EPA, 2013a, section 6.2.3.2). Because associations with inflammation were attenuated with higher antioxidant intake in the study by Sienra-Monge et al. (2004), this study provides additional evidence that inhaled O_3 is likely to be an important source of reactive oxygen species in airways and/or may increase pulmonary inflammation via oxidative stress-mediated mechanisms among all age groups. Limitations in some recent studies have contributed to inconsistent results in adults (U.S. EPA, 2013a, section 6.2.3.2).

Exposure to ambient O_3 on multiple days can result in larger increases in pulmonary inflammation and oxidative stress, as discussed in section 6.2.3.2 of the ISA (U.S. EPA, 2013a). In studies that examined multiple O_3 lags,

reported increased symptoms in addition to inflammation.

[48] Exhaled NO has been shown to be a useful biomarker for airway inflammation in large population-based studies (Linn et al., 2009) (U.S. EPA, 2013a, section 7.2.4).

multiday averages of 8-hour maximum or 8-hour average concentrations were associated with larger increases in pulmonary inflammation and oxidative stress (Berhane et al., 2011; Delfino et al., 2010; Sienra-Monge et al., 2004), consistent with controlled human exposure (U.S. EPA, 2013a, section 6.2.3.1) and animal studies (U.S. EPA, 2013a, section 6.2.3.3) reporting that some markers of pulmonary inflammation remain elevated with O_3 exposures repeated over multiple days. Evidence from animal toxicological studies also clearly indicates that O_3 exposures result in damage and inflammation in the lung (U.S. EPA, 2013a, section 5.3). In the few studies that evaluated the potential for confounding, O_3 effect estimates were not confounded by temperature or humidity, and were robust to adjustment for $PM_{2.5}$ or PM_{10} (Barraza-Villarreal et al., 2008; Romieu et al., 2008; Sienra-Monge et al., 2004).

In conclusion, a relatively small number of controlled human exposure studies evaluating O_3-induced airway inflammation have become available since the last review. For purposes of reviewing the current O_3 NAAQS, the most important of these recent studies reported a statistically significant increase in airway inflammation in healthy adults at moderate exertion following exposures to 60 ppb O_3, the lowest concentration that has been evaluated for inflammation. In addition, a number of recent epidemiologic studies report O_3-associated increases in markers of pulmonary inflammation, particularly in children. Thus, recent studies continue to support the evidence for airway inflammation and injury that was available in previous reviews, with new evidence for such effects following exposures to lower concentrations than had been evaluated previously.

iii. Airway Hyperresponsiveness

Airway hyperresponsiveness (AHR) refers to a condition in which the conducting airways undergo enhanced bronchoconstriction in response to a variety of stimuli. Airway hyperresponsiveness is an important consequence of exposure to ambient O_3 because its presence reflects a change in airway smooth muscle reactivity, and indicates that the airways are predisposed to narrowing upon inhalation of a variety of ambient stimuli including specific triggers (*i.e.,* allergens) and nonspecific triggers (*e.g.,* SO_2, and cold air). People with asthma are generally more sensitive to bronchoconstricting agents than those without asthma, and the use of an airway challenge to inhaled bronchoconstricting agents is a diagnostic test in asthma (U.S. EPA, 2013, section 6.2.2). Standards for airway responsiveness testing have been developed for the clinical laboratory (ATS, 2000), although variation in the methodology for administering the bronchoconstricting agent may affect the results (Cockcroft et al., 2005). There is a wide range of airway responsiveness in people without asthma, and responsiveness is influenced by a number of factors, including cigarette smoke, pollutant exposures, respiratory infections, occupational exposures, and respiratory irritants. Dietary antioxidants have been reported to attenuate O_3-induced bronchial hyperresponsiveness in people with asthma (Trenga et al., 2001).

Evidence for airway hyperresponsiveness (AHR) following O_3 exposures is derived primarily from controlled human exposure and toxicological studies (U.S. EPA, 2013a, section 6.2.2). Airway responsiveness is often quantified by measuring changes in pulmonary function following the inhalation of an aerosolized allergen or a nonspecific bronchoconstricting agent (*e.g.,* methacholine), or following exposure to a bronchoconstricting stimulus such as cold air. In the last review, controlled human exposure studies of mostly adults (≥18 years of age) had shown that exposures to O_3 concentrations at or above 80 ppb increase airway responsiveness, as indicated by a reduction in the concentration of specific (*e.g.,* ragweed) and non-specific (*e.g.,* methacholine) agents required to produce a given reduction in lung function (*e.g.,* as measured by FEV_1 or specific airway resistance) (U.S. EPA, 2013a, section 6.2.2.1). This O_3-induced AHR has been reported to be dose-dependent (Horstman et al., 1990). Animal toxicology studies have reported O_3-induced AHR in a number of species, with some rat strains exhibiting hyperresponsiveness following 4-hour exposures to O_3 concentrations as low as 50 ppb (Depuydt et al., 1999). Since the last review, there have been relatively few new controlled human exposure and animal toxicology studies of O_3 and AHR, and no new studies have evaluated exposures to O_3 concentrations at or below 80 ppb (U.S. EPA, 2013a, section 6.2.2.1).

Airway hyperresponsiveness is linked with the accumulation and/or activation of eosinophils in the airways of asthmatics, which is followed by production of mucus and a late-phase asthmatic response (section II.B.4.a.ii). In a study of 16 intermittent asthmatics, Hiltermann et al. (1999) found that there was a significant inverse correlation between the O_3-induced change in the percentage of eosinophils in induced sputum and the concentration of methacholine causing a 20% decrease in FEV_1. Hiltermann et al. (1999) concluded that the results point to the role of eosinophils in O_3-induced AHR. Increases in O_3-induced nonspecific airway responsiveness incidence and duration could have important clinical implications for children and adults with asthma, such as exacerbations of their disease.

Airway hyperresponsiveness after O_3 exposure appears to resolve more slowly than changes in FEV_1 or respiratory symptoms (Folinsbee and Hazucha, 2000). Studies suggest that O_3-induced AHR usually resolves 18 to 24 hours after exposure, but may persist in some individuals for longer periods (Folinsbee and Hazucha, 1989). Furthermore, in studies of repeated exposure to O_3, changes in AHR tend to be somewhat less susceptible to attenuation with consecutive exposures than changes in FEV_1 (Gong et al., 1997; Folinsbee et al., 1994; Kulle et al., 1982; Dimeo et al., 1981) (U.S. EPA, 2013a, section 6.2.2). In animal studies a 3-day continuous exposure resulted in attenuation of O_3-induced AHR (Johnston et al., 2005) while repeated exposures for 2 hours per day over 10 days did not (Chhabra et al., 2010), suggesting that attenuation could be lost when repeated exposures are interspersed with periods of rest (U.S. EPA, 2013a, section 6.2.2.2).

As mentioned above, in addition to human subjects a number of species, including nonhuman primates, dogs, cats, rabbits, and rodents, have been used to examine the effect of O_3 exposure on AHR, (U.S. EPA, 1996, Table 6–14; and U.S. EPA, 2006a, *Annex Table AX5–12, p. AX5–36*). A body of animal toxicology studies, including some recent studies conducted since the last review, provides support for the O_3-induced AHR reported in humans (U.S. EPA, 2013a, section 6.2.2.2). Although most of these studies evaluated O_3 concentrations above those typically found in ambient air in cities in the United States (*i.e.,* most studies evaluated O_3 concentrations of 100 ppb or greater), one study reported that a very low exposure concentration (50 ppb for 4 hours) induced AHR in some rat strains (Depuydt et al., 1999). Additional recent rodent studies reported O_3-induced AHR following exposures to O_3 concentrations from 100 to 500 ppb (Johnston et al., 2005; Chhabra et al., 2010; Larsen et al., 2010).

In characterizing the relevance of these exposure concentrations, the ISA noted that a study using radiolabeled O_3 suggests that even very high O_3 exposure concentrations in rodents could be equivalent to much lower exposure concentrations in humans. Specifically, a 2000 ppb (2 ppm) O_3 exposure concentration in resting rats was reported to be roughly equivalent to a 400 ppb exposure concentration in exercising humans (Hatch et al., 1994). Given this relationship, the ISA noted that animal data obtained in resting conditions could underestimate the risk of effects for humans (U.S. EPA, 2013a, section 2.4, p. 2–14).

The 2006 AQCD (U.S. EPA, 2006a, p. 6–34) concluded that spirometric responses to O_3 are independent of inflammatory responses and markers of epithelial injury (Balmes et al., 1996; Blomberg et al., 1999; Torres et al., 1997). Significant inflammatory responses to O_3 exposures that did not elicit significant spirometric responses have been reported (Holz et al., 2005). A recent study (Que et al., 2011) indicates that AHR also appears to be mediated by a differing physiologic pathway. These results from controlled human exposure studies indicate that O_3-induced lung function decrements, inflammatory responses and pulmonary injury (leading to increased epithelial permeability), and AHR, are mediated by apparently different physiologic pathways. Except for lung function decrements, we do not have concentration or exposure response information about the other, potentially more sensitive,[49] clinical endpoints (*i.e.,* inflammation, increased epithelial permeability, AHR) that would allow us to quantitatively estimate the size of the population affected and the magnitude of their responses.

In summary, a strong body of controlled human exposure and animal toxicological studies, most of which were available in the last review of the O_3 NAAQS, report O_3-induced AHR after either acute or repeated exposures (U.S. EPA, 2013a, section 6.2.2.2). People with asthma often exhibit increased airway responsiveness at baseline relative to healthy controls, and they can experience further increases in responsiveness following exposures to O_3. Studies reporting increased airway responsiveness after O_3 exposure contribute to a plausible link between ambient O_3 exposures and increased respiratory symptoms in asthmatics, and increased hospital admissions and emergency department visits for asthma (U.S. EPA, 2013a, section 6.2.2.2).

iv. Respiratory Symptoms and Medication Use

Respiratory symptoms are associated with adverse outcomes such as limitations in activity, and are the primary reason for people with asthma to use quick relief medication and seek medical care. Studies evaluating the link between O_3 exposures and such symptoms allow a direct characterization of the clinical and public health significance of ambient O_3 exposure. Controlled human exposure and toxicological studies have described modes of action through which short-term O_3 exposures may increase respiratory symptoms by demonstrating O_3-induced AHR (U.S. EPA, 2013a, section 6.2.2) and pulmonary inflammation (U.S. EPA, 2013a, section 6.2.3).

The link between subjective respiratory symptoms and O_3 exposures has been evaluated in both controlled human exposure and epidemiologic studies, and the link with medication use has been evaluated in epidemiologic studies. In the last review, several controlled human exposure studies reported respiratory symptoms following exposures to O_3 concentrations at or above 80 ppb. In addition, one study reported such symptoms following exposures to 60 ppb O_3, though the increase was not statistically different from filtered air controls. Epidemiologic studies reported associations between ambient O_3 and respiratory symptoms and medication use in a variety of locations and populations, including asthmatic children living in U.S. cities. In the current review, additional controlled human exposure studies have evaluated respiratory symptoms following exposures to O_3 concentrations below 80 ppb and recent epidemiologic studies have evaluated associations with respiratory symptoms and medication use (U.S. EPA, 2013a, sections 6.2.1, 6.2.4).

In controlled human exposure studies available in the last review as well as newly available studies, statistically significant increases in respiratory symptoms have been reported in healthy adult volunteers engaged in intermittent, moderate exertion following 6.6 hour exposures to average O_3 concentrations of 80 ppb (Adams, 2003; Adams, 2006; Schelegle et al., 2009) and 72 ppb (Schelegle et al., 2009). Such symptoms have been reported to increase with increasing O_3 exposure concentrations, duration of exposure, and activity level (McDonnell et al., 1999).

Results have been less consistent for lower exposure concentrations. A recent study by Schelegle et al. (2009) reported a statistically significant increase in respiratory symptoms in healthy adults following 6.6 hour exposures to an average O_3 concentration of 72 ppb, but not 60 ppb. Kim et al. (2011) also did not find statistically significant increases in respiratory symptoms following exposures of healthy adults to 60 ppb O_3. Adams (2006) reported an increase in respiratory symptoms in healthy adults during a 6.6 hour exposure protocol with an average O_3 exposure concentration of 60 ppb. This increase was significantly different from initial respiratory symptoms, but not from filtered air controls. The findings for O_3-induced respiratory symptoms in controlled human exposure studies, and the evidence integrated across disciplines describing underlying modes of action, provide biological plausibility for epidemiologic associations observed between short-term increases in ambient O_3 concentration and increases in respiratory symptoms (U.S. EPA, 2013a, section 6.2.4).

In epidemiologic panel studies of respiratory symptoms, data typically are collected by having subjects (or their parents) record symptoms and medication use in a diary without direct supervision by study staff. Several limitations of symptom reports are well recognized, as described in the ISA (U.S. EPA, 2013a, section 6.2.4). Nonetheless, symptom diaries remain a convenient tool to collect individual-level data from a large number of subjects and allow modeling of associations between daily changes in O_3 concentration and daily changes in respiratory morbidity over multiple weeks or months. Importantly, many of the limitations in these studies are sources of random measurement error that can bias effect estimates to the null or increase the uncertainty around effect estimates (U.S. EPA, 2013a, section 6.2.4). Because respiratory symptoms are associated with limitations in activity and daily function and are the primary reason for using medication and seeking medical care, the evidence is directly coherent with the associations consistently observed between increases in ambient O_3 concentration and increases in asthma emergency department visits, discussed below (U.S. EPA, 2013a, section 6.2.4).

Most epidemiologic studies of O_3 and respiratory symptoms and medication use have been conducted in children

[49] CASAC noted that ''while measures of FEV1 are quantitative and readily obtainable in humans, they are not the only measures—and perhaps not the most sensitive measures—of the adverse health effects induced by ozone exposure.'' (Henderson, 2006).

and/or adults with asthma, with fewer studies, and less consistent results, in non-asthmatic populations (U.S. EPA, 2013a, section 6.2.4). The 2006 AQCD (U.S. EPA, 2006a, U.S. EPA, 2013a, section 6.2.4) concluded that the collective body of epidemiologic evidence indicated that short-term increases in ambient O_3 concentrations are associated with increases in respiratory symptoms in children with asthma. A large body of single-city and single-region studies of asthmatic children provides consistent evidence for associations between short-term increases in ambient O_3 concentrations and increased respiratory symptoms and asthma medication use in children with asthma (U.S. EPA, 2013a, Figure 6–12, Table 6–20, p. 79).

Methodological differences among studies make comparisons across recent multicity studies of respiratory symptoms difficult. Because of fewer person-days of data (Schildcrout et al., 2006) or examination of 19-day averages of ambient O_3 concentrations (O'Connor et al., 2008), the ISA did not give greater weight to results from recent multicity studies than results from single-city studies (U.S. EPA, 2013a, section 6.2.4.5).[50] While evidence from the few available U.S. multicity studies is less consistent (O'Connor et al., 2008; Schildcrout et al., 2006; Mortimer et al., 2002), the overall body of epidemiologic evidence with respect to the association betweeen exposure to O_3 and respiratory symptoms in asthmatic children remains compelling (U.S. EPA, 2013a, section 6.2.4.1). Findings from a small body of studies indicate that O_3 is also associated with increased respiratory symptoms in adults with asthma (Khatri et al., 2009; Feo Brito et al., 2007; Ross et al., 2002) (U.S. EPA, 2013a, section 6.2.4.2).

Available evidence indicates that O_3-associated increases in respiratory symptoms are not confounded by temperature, pollen, or copollutants (primarily PM) (U.S. EPA, 2013a, section 6.2.4.5; Table 6–25; Romieu et al., 1996; Romieu et al., 1997; Thurston et al., 1997; Gent et al., 2003). However, identifying the independent effects of O_3 in some studies was complicated due to the high correlations observed between O_3 and PM or different lags and averaging times examined for copollutants. Nonetheless, the ISA noted that the robustness of associations in some studies of individuals with asthma, combined with findings from controlled human exposure studies for the direct effects of O_3 exposure, provide substantial evidence supporting the independent effects of short-term ambient O_3 exposure on respiratory symptoms (U.S. EPA, 2013a, section 6.2.4.5).

Epidemiologic studies of medication use have reported associations with 1-hour maximum O_3 concentrations and with multiday average O_3 concentrations (Romieu et al., 2006; Just et al., 2002). Some studies reported O_3 associations for both respiratory symptoms and asthma medication use (Escamilla-Nuñez et al., 2008; Romieu et al., 2006; Schildcrout et al., 2006; Jalaludin et al., 2004; Romieu et al., 1997; Thurston et al., 1997) while others reported associations for either respiratory symptoms or medication use (Romieu et al., 1996; Rabinovitch et al., 2004; Just et al., 2002; Ostro et al., 2001).

In summary, both controlled human exposure and epidemiologic studies have reported respiratory symptoms attributable to short-term O_3 exposures. In the last review, the majority of the evidence from controlled human exposure studies in young, healthy adults was for symptoms following exposures to O_3 concentrations at or above 80 ppb. Although studies that have become available since the last review have not reported increased respiratory symptoms in young, healthy adults following exposures with moderate exertion to 60 ppb, one recent study did report increased symptoms following exposure to 72 ppb O_3. As was concluded in the 2006 O_3 AQCD (U.S. EPA, 2006a; U.S. EPA, 1996), the collective body of epidemiologic evidence indicates that short-term increases in ambient O_3 concentration are associated with increases in respiratory symptoms in children with asthma (U.S. EPA, 2013a, section 6.2.4). Recent studies of respiratory symptoms and medication use, primarily in asthmatic children, add to this evidence. In a smaller body of studies, increases in ambient O_3 concentration were associated with increases in respiratory symptoms in adults with asthma.

v. Lung Host Defense

The mammalian respiratory tract has a number of closely integrated defense mechanisms that, when functioning normally, provide protection from the potential health effects of exposures to a wide variety of inhaled particles and microbes. These defense mechanisms include mucociliary clearance, alveolobronchiolar transport mechanism, alveolar macrophages,[51] and adaptive immunity[52] (U.S. EPA, 2013a, section 6.2.5). The previous O_3 AQCD (U.S. EPA, 2006a) concluded that animal toxicological studies provided evidence that acute exposure to O_3 concentrations as low as 100 to 500 ppb can increase susceptibility to infectious diseases due to modulation of these lung host defenses. This conclusion was based, in large part, on animal studies of alveolar macrophage function and mucociliary clearance (U.S. EPA, 2013a, section 6.2.5).

Integrating animal study results with human exposure evidence, the 2006 Criteria Document concluded that available evidence indicates that short-term O_3 exposures have the potential to impair host defenses in humans, primarily by interfering with alveolar macrophage function. Any impairment in alveolar macrophage function may lead to decreased clearance of microorganisms or nonviable particles. Compromised alveolar macrophage functions in asthmatics may increase their susceptibility to other O_3 effects, the effects of particles, and respiratory infections (U.S. EPA, 2006a, p. 8–26). These conclusions were based largely on studies conducted in animals exposed for several hours up to several weeks to O_3 concentrations from 100 to 250 ppb (Hurst et al., 1970; Driscoll et al., 1987; Cohen et al., 2002). Consistent with the animal evidence, a controlled human exposure study available in the last review had reported decrements in the ability of alveolar macrophages to phagocytize yeast following exposures of healthy volunteers to O_3 concentrations of 80 and 100 ppb for 6.6 hours during moderate exercise (Devlin et al., 1991).

Alveolobronchiolar transport mechanisms refers to the transport of particles deposited in the deep lung (alveoli) which may be removed either up through the respiratory tract (bronchi) by alveolobronchiolar transport or through the lymphatic system. The pivotal mechanism of alveolobronchiolar transport involves the movement of alveolar macrophages with ingested particles to the bottom of the conducting airways. These airways are lined with ciliated epithelial cells and cells that produce mucous, which surrounds the macrophages. The ciliated epithelial cells move the

[50] Though, as discussed below, for other endpoints (*e.g.,* hospital admissions, emergency department visits) the ISA focused primarily on multicity studies.

[51] Phagocytic white blood cells within the alveoli of the lungs that ingest inhaled particles.

[52] The adaptive immune system, is also known as the acquired immune system. Acquired immunity creates immunological memory after an initial response to a specific pathogen, leading to an enhanced response to subsequent encounters with that same pathogen.

mucous packets up the resiratory tract, hence the term ''mucociliary escalator.'' Although some studies show reduced tracheobronchial clearance after O_3 exposure (U.S. EPA, 2013a, section 6.2.5.1), alveolar clearance of deposited material is accelerated, presumably due to macrophage influx, which in itself can be damaging.

With regard to adaptive immunity, a limited number of epidemiologic studies have examined associations between O_3 exposure and hospital admissions or emergency department visits for respiratory infection, pneumonia, or influenza. Results have been mixed, and in some cases conflicting (U.S. EPA, 2013a, sections 6.2.7.2 and 6.2.7.3). With the exception of influenza, it is difficult to ascertain whether cases of respiratory infection or pneumonia are of viral or bacterial etiology. A recent study that examined the association between O_3 exposure and respiratory hospital admissions in response to an increase in influenza intensity observed an increase in respiratory hospital admissions (Wong et al., 2009), but information from toxicological studies of O_3 and viral infections is ambiguous.

In summary, relatively few studies conducted since the last review have evaluated the effects of O_3 exposures on lung host defense. When the available evidence is taken as a whole, the ISA concludes that acute O_3 exposures impair the host defense capability of animals, primarily by depressing alveolar macrophage function and perhaps also by decreasing mucociliary clearance of inhaled particles and microorganisms. Coupled with limited evidence from controlled human exposure studies, this suggests that humans exposed to O_3 could be predisposed to bacterial infections in the lower respiratory tract (U.S. EPA, 2013a, section 6.2.5.5).

vi. Allergic and Asthma-Related Responses

Effects resulting from combined exposures to O_3 and allergens have been studied in a variety of animal species, generally as models of experimental asthma. Pulmonary function and AHR in animal models of asthma are discussed in detail in Section 6.2.1.3 and Section 6.2.2.2, respectively, in the ISA (U.S. EPA, 2013a). Studies of allergic and asthma-related responses are discussed in detail in sections 5.3.6 and 6.2.6 of the ISA (U.S. EPA, 2013a).

Evidence available in the last review indicates that O_3 exposure skews immune responses toward an allergic phenotype and could also make airborne allergens more allergenic. In humans, allergic rhinoconjunctivitis symptoms are associated with increases in ambient O_3 concentrations (Riediker et al., 2001). Controlled human exposure studies have observed O_3-induced changes indicating allergic skewing. Airway eosinophils, which are white blood cells that participate in allergic disease and inflammation, were observed to increase in volunteers with atopy [53] and mild asthma (Peden et al., 1997). In a more recent study, expression of IL–5, a cytokine involved in eosinophil recruitment and activation, was increased in subjects with atopy but not in healthy subjects (Hernandez et al., 2010). Epidemiologic studies describe associations between eosinophils in both short- (U.S. EPA, 2013a, section 6.2.3.2) and long-term (U.S. EPA, 2013a, section 7.2.5) O_3 exposure, as do chronic exposure studies in non-human primates. Collectively, findings from these studies suggest that O_3 can induce or enhance certain components of allergic inflammation in individuals with allergy or allergic asthma.

Evidence available in the last review indicates that O_3 may also increase AHR to specific allergen triggers (75 FR 2970, January 19, 2010). Two studies (Jörres et al., 1996; Holz et al., 2002) observed increased airway responsiveness to O_3 exposure with bronchial allergen challenge in subjects with preexisting allergic airway disease. Ozone-induced exacerbation of airway responsiveness persists longer and attenuates more slowly than O_3-induced lung function decrements and respiratory symptom responses and can have important clinical implications for asthmatics. Animal toxicology studies indicate that O_3 enhances inflammatory and allergic responses to allergen challenge in sensitized animals. In addition to exacerbating existing allergic responses, toxicology studies indicate that O_3 can also act as an adjuvant to produce sensitization in the respiratory tract. Along with its pro-allergic effects (inducing or enhancing certain components of allergic inflammation in individuals with allergy or allergic asthma), O_3 could also make airborne allergens more allergenic. When combined with NO_2, O_3 has been shown to enhance nitration of common protein allergens, which may increase their allergenicity (Franze et al., 2005).

[53] Atopy is a predisposition toward developing certain allergic hypersensitivity reactions. A person with atopy typically presents with one or more of the following: eczema (atopic dermatitis), allergic rhinitis (hay fever), allergic conjunctivitis, or allergic asthma.

vii. Hospital Admissions and Emergency Department Visits

The 2006 O_3 AQCD evaluated numerous studies of respiratory-related emergency department visits and hospital admissions. These were primarily time-series studies conducted in the U.S., Canada, Europe, South America, Australia, and Asia. Based on such studies, the 2006 O_3 AQCD concluded that ''the overall evidence supports a causal relationship between acute ambient O_3 exposures and increased respiratory morbidity resulting in increased emergency department visits and [hospital admissions] during the warm season'' [54] (U.S. EPA, 2006a). This conclusion was ''strongly supported by the human clinical, animal toxicologic[al], and epidemiologic evidence for [O_3-induced] lung function decrements, increased respiratory symptoms, airway inflammation, and airway hyperreactivity'' (U.S. EPA, 2006a).

The results of recent studies largely support the conclusions of the 2006 O_3 AQCD (U.S. EPA, 2013a, section 6.2.7). Since the completion of the 2006 O_3 AQCD, relatively fewer studies conducted in the U.S., Canada, and Europe have evaluated associations between short-term O_3 concentrations and respiratory hospital admissions and emergency department visits, with a growing number of studies conducted in Asia. This epidemiologic evidence is discussed in detail in the ISA (U.S. EPA, 2013a, section 6.2.7).[55]

In considering this body of evidence, the ISA focused primarily on multicity studies because they examine associations with respiratory-related hospital admissions and emergency department visits over large geographic areas using consistent statistical methodologies (U.S. EPA, 2013a, section 6.2.7.1). The ISA also focused on single-city studies that encompassed a large number of daily hospital admissions or emergency department visits, included long study-durations, were conducted in locations not represented by the larger studies, or examined population-specific characteristics that may impact the risk of O_3-related health effects but were not evaluated in the larger studies (U.S. EPA, 2013a, section 6.2.7.1). When

[54] Epidemiologic associations for O_3 are more robust during the warm season than during cooler months (*e.g.,* smaller measurement error, less potential confounding by copollutants). Rationale for focusing on warm season epidemiologic studies for O_3 can be found at 72 FR 37838–37840.

[55] The consideration of ambient O_3 concentrations in the locations of these epidemiologic studies are discussed in sections II.D.1.b and II.E.4.a below, for the current standard and alternative standards, respectively.

examining the association between short-term O_3 exposure and respiratory health effects that require medical attention, the ISA distinguishes between hospital admissions and emergency department visits because it is likely that a small percentage of respiratory emergency department visits will be admitted to the hospital; therefore, respiratory emergency department visits may represent potentially less serious, but more common outcomes (U.S. EPA, 2013a, section 6.2.7.1).

Several recent multicity studies (*e.g.,* Cakmak et al., 2006; Dales et al., 2006) and a multi-continent study (Katsouyanni et al., 2009) report associations between short-term O_3 concentrations and increased respiratory-related hospital admissions and emergency department visits. These multicity studies are supported by results from single-city studies also reporting consistent positive associations using different exposure assignment approaches (*i.e.,* average of multiple monitors, single monitor, population-weighted average) and averaging times (*i.e.,* 1-hour max and 8-hour max) (U.S. EPA, 2013a, sections 6.2.7.1 to 6.2.7.5). When examining cause-specific respiratory outcomes, recent studies report positive associations with hospital admissions and emergency department visits for asthma (Strickland et al., 2010; Stieb et al., 2009) and chronic obstructive pulmonary disease (COPD) (Stieb et al., 2009; Medina-Ramon et al., 2006), with more limited evidence for pneumonia (Medina-Ramon et al., 2006; Zanobetti and Schwartz, 2006). In seasonal analyses (U.S. EPA, 2013a, Figure 6–19, Table 6–28), stronger associations were reported in the warm season or summer months, when O_3 concentrations are higher, compared to the cold season, particularly for asthma (Strickland et al., 2010; Ito et al., 2007) and COPD (Medina-Ramon et al., 2006). The available evidence indicates that children are at greatest risk for effects leading to O_3-associated hospital admissions and emergency department visits (Silverman and Ito, 2010; Mar and Koenig, 2009; Villeneuve et al., 2007).

Although the collective evidence across studies indicates a mostly consistent positive association between O_3 exposure and respiratory-related hospital admissions and emergency department visits, the magnitude of these associations may be underestimated to the extent members of study populations modify their behavior in response to air quality forecasts, and to the extent such behavior modification increases exposure misclassification (U.S. EPA, 2013, Section 4.6.6). Studies examining the potential confounding effects of copollutants have reported that O_3 effect estimates remained relatively robust upon the inclusion of PM and gaseous pollutants in two-pollutant models (U.S. EPA, 2013a, Figure 6–20, Table 6–29). Additional studies that conducted copollutant analyses, but did not present quantitative results, also support these conclusions (Strickland et al., 2010; Tolbert et al., 2007; Medina-Ramon et al., 2006) (U.S. EPA, 2013a, section 6.2.7.5).

In the last review, studies had not evaluated the concentration-response relationship between short-term O_3 exposure and respiratory-related hospital admissions and emergency department visits. A preliminary examination of this relationship in studies that have become available since the last review found no evidence of a deviation from linearity when examining the association between short-term O_3 exposure and asthma hospital admissions (U.S. EPA, 2013a, page 6–157; Silverman and Ito, 2010). In addition, an examination of the concentration-response relationship for O_3 exposure and pediatric asthma emergency department visits found no evidence of a threshold at O_3 concentrations as low as 30 ppb (for daily maximum 8-hour concentrations) (Strickland et al., 2010). However, in both studies there is uncertainty in the shape of the concentration-response curve at the lower end of the distribution of O_3 concentrations due to the low density of data in this range (U.S. EPA, 2013a, page 6–157).

viii. Respiratory Mortality

The controlled human exposure, epidemiologic, and toxicological studies discussed in section 6.2 of the ISA (U.S. EPA, 2013a) provide evidence for respiratory morbidity effects, including emergency department visits and hospital admissions, in response to short-term O_3 exposures. Moreover, evidence from experimental studies indicates multiple potential pathways of respiratory effects from short-term O_3 exposures, which support the continuum of respiratory effects that could potentially result in respiratory-related mortality in adults (U.S. EPA, 2013a, section 6.2.8). The 2006 O_3 AQCD found inconsistent evidence for associations between short-term O_3 concentrations and respiratory mortality (U.S. EPA, 2006a). Although some studies reported a strong positive association between O_3 and respiratory mortality, additional studies reported small associations or no associations. New epidemiologic evidence for respiratory mortality is discussed in detail in section 6.2.8 of the ISA (U.S. EPA, 2013a). The majority of recent multicity studies have reported positive associations between short-term O_3 exposures and respiratory mortality, particularly during the summer months (U.S. EPA, 2013a, Figure 6–36).

Specifically, recent multicity studies from the U.S. (Zanobetti and Schwartz, 2008b), Europe (Samoli et al., 2009), Italy (Stafoggia et al., 2010), and Asia (Wong et al., 2010), as well as a multi-continent study (Katsouyanni et al., 2009), reported associations between short-term O_3 concentrations and respiratory mortality (U.S. EPA, 2013a, Figure 6–37, page 6–259). With respect to respiratory mortality, summer-only analyses were consistently positive and most were statistically significant. All-year analyses had more mixed results, but most were positive.

Of the studies evaluated, only the studies by Katsouyanni et al. (2009) and by Stafoggia et al. (2010) analyzed the potential for copollutant confounding of the O_3-respiratory mortality relationship. Based on the results of these analyses, the ISA concluded that O_3 respiratory mortality risk estimates appear to be moderately to substantially sensitive (*e.g.,* increased or attenuated) to inclusion of PM_{10}. However, in the APHENA study (Katsouyanni et al., 2009), the mostly every-6th-day sampling schedule for PM_{10} in the Canadian and U.S. datasets greatly reduced their sample size and limits the interpretation of these results (U.S. EPA, 2013a, section 6.2.8).

In summary, recent epidemiologic studies support and reinforce the epidemiologic evidence for O_3-associated respiratory hospital admissions and emergency department visits from the last review. In addition, the evidence for associations with respiratory mortality has been strengthened since the last review, with the addition of several large multicity studies. The biological plausibility of the associations reported in these studies is supported by the experimental evidence for respiratory effects.

b. Respiratory Effects—Long-Term

Since the last review, the body of evidence indicating the occurrence of respiratory effects due to long-term O_3 exposure has been strengthened. This evidence is discussed in detail in the ISA (U.S. EPA, 2013a, Chapter 7) and summarized below for new-onset asthma and asthma prevalence, asthma hospital admissions, pulmonary structure and function, and respiratory mortality.

i. New-Onset Asthma and Asthma Prevalence

Asthma is a heterogeneous disease with a high degree of temporal variability. The on-set, progression, and symptoms can vary within an individual's lifetime, and the course of asthma may vary markedly in young children, older children, adolescents, and adults. In the previous review, longitudinal cohort studies that examined associations between long-term O_3 exposures and the onset of asthma in adults and children indicated a direct effect of long-term O_3 exposures on asthma risk in adults (McDonnell et al., 1999, 15-year follow-up; Greer et al., 1993, 10-year follow-up) and effect modification by O_3 in children (McConnell et al., 2002). Since that review, additional studies have evaluated associations with new onset asthma, further informing our understanding of the potential gene-environment interactions, mechanisms, and biological pathways associated with incident asthma.

In children, the relationship between long-term O_3 exposure and new-onset asthma has been extensively studied in the Children's Health Study (CHS), a long-term study that was initiated in the early 1990's which has evaluated effects in several cohorts of children. The CHS was initially designed to examine whether long-term exposure to ambient pollution was related to chronic respiratory outcomes in children in 12 communities in southern California. In the CHS, new-onset asthma was classified as having no prior history of asthma at study entry with subsequent report of physician-diagnosed asthma at follow-up, with the date of onset assigned to be the midpoint of the interval between the interview date when asthma diagnosis was first reported and the previous interview date. The results of one study (McConnell et al., 2002) available in the previous review indicated that within high O_3 communities, asthma risk was 3.3 times greater for children who played three or more outdoor sports as compared with children who played no sports.

For this review, as discussed in section 7.2.1.1 of the ISA (U.S. EPA, 2013a), recent studies from the CHS provide evidence for gene-environment interactions in effects on new-onset asthma by indicating that the lower risks associated with specific genetic variants are found in children who live in lower O_3 communities. These studies indicate that the risk for new-onset asthma is related in part to genetic susceptibility, as well as behavioral factors and environmental exposure. The onset of a chronic disease, such as asthma, is partially the result of a sequence of biochemical reactions involving exposures to various environmental agents metabolized by enzymes related to a number of different genes. Oxidative stress has been proposed to underlie the mechanistic hypotheses related to O_3 exposure. Genetic variants may impact disease risk directly, or modify disease risk by affecting internal dose of pollutants and other environmental agents and/or their reaction products, or by altering cellular and molecular modes of action. Understanding the relation between genetic polymorphisms and environmental exposure can help identify high-risk subgroups in the population and provide better insight into pathway mechanisms for these complex diseases.

The CHS analyses (Islam et al., 2008; Islam et al., 2009; Salam et al., 2009) have found that asthma risk is related to interactions between O_3 and variants in genes for enzymes such as heme-oxygenase (HO–1), arginases (ARG1 and 2), and glutathione S transferase P1 (GSTP1). Biological plausibility for these findings is provided by evidence that these enzymes have antioxidant and/or anti-inflammatory activity and participate in well-recognized modes of action in asthma pathogenesis. As O_3 is a source of oxidants in the airways, oxidative stress serves as the link among O_3 exposure, enzyme activity, and asthma. Further, several lines of evidence demonstrate that secondary oxidation products of O_3 initiate the key modes of action that mediate downstream health effects (U.S. EPA, 2013a, section 5.3). For example, HO–1 responds rapidly to oxidants, has anti-inflammatory and antioxidant effects, relaxes airway smooth muscle, and is induced in the airways during asthma. Cross-sectional studies by Akinbami et al. (2010) and Hwang et al. (2005) provide further evidence relating O_3 exposures with asthma prevalence. Gene-environment interactions are discussed in detail in Section 5.4.2.1 in the ISA (U.S. EPA, 2013a).

ii. Asthma Hospital Admissions

In the 2006 AQCD, studies on O_3-related hospital discharges and emergency department visits for asthma and respiratory disease mainly looked at short-term (daily) metrics. The short-term O_3 studies presented in section 6.2.7.5 of the ISA (U.S. EPA, 2013a) and discussed above in section 3.1.2.1 continue to indicate that there is evidence for increases in both hospital admissions and emergency department visits in children and adults related to all respiratory outcomes, including asthma, with stronger associations in the warm months. New studies, discussed in section 7.2.2 of the ISA (U.S. EPA, 2013a) also evaluated long-term O_3 exposure metrics, providing a new line of evidence that suggests a positive exposure-response relationship between the first hospital admission for asthma and long-term O_3 exposure, although the ISA cautions in attributing the associations in that study to long-term exposures since there is potential for short-term exposures to contribute to the observed associations.

Evidence associating long-term O_3 exposure to first asthma hospital admission in a positive concentration-response relationship is provided in a retrospective cohort study (Lin et al., 2008b). This study investigated the association between chronic exposure to O_3 and childhood asthma admissions by following a birth cohort of more than 1.2 million babies born in New York State (1995–1999) to first asthma admission or until December 31, 2000. Three annual indicators (all 8-hour maximum from 10:00 a.m. to 6:00 p.m.) were used to define chronic O_3 exposure: (1) Mean concentration during the follow-up period (41.06 ppb); (2) mean concentration during the O_3 season (50.62 ppb); and (3) proportion of follow-up days with O_3 levels >70 ppb. The effects of copollutants were controlled, and interaction terms were used to assess potential effect modifications. A positive association between chronic exposure to O_3 and childhood asthma hospital admissions was observed, indicating that children exposed to high O_3 levels over time are more likely to develop asthma severe enough to be admitted to the hospital. The various factors were examined and differences were found for younger children (1–2 years), poor neighborhoods, Medicaid/self-paid births, geographic region and others. As shown in the ISA, Figure 7–3 (U.S. EPA, 2013a, p. 7–16), positive concentration-response relationships were observed. Asthma admissions were significantly associated with increased O_3 levels for all chronic exposure indicators.

In considering the relationship between long-term pollutant exposures and chronic disease health endpoints, where chronic pathologies are found with acute expression of chronic disease, Künzli (2012) hypothesizes that if the associations of pollution with events are much larger in the long-term studies, it provides some indirect evidence that air pollution increases the pool of subjects with chronic disease, and that more acute events are to be

expected to be seen for higher exposures. The results of Lin et al (2008a) for first asthma hospital admission, presented in Figure 7–3 (U.S. EPA, 2013a, p. 7–16), show effects estimates that are larger than those reported in a study of childhood asthma hospital admission in New York State (Silverman and Ito, 2010), discussed above. The ISA (U.S. EPA, 2013a, p. 7–16) notes that this provides some support for the hypothesis that O_3 exposure may not only have triggered the events but also increased the pool of asthmatic children, but cautions in attributing the associations in the Lin et al. (2008) study to long-term exposures since there is potential for short-term exposures to contribute to the observed associations.

iii. Pulmonary Structure and Function

In the 2006 O_3 AQCD, few epidemiologic studies had investigated the effect of chronic O_3 exposure on pulmonary function. The definitive 8-year follow-up analysis of the first cohort of the CHS (U.S. EPA, 2013a, section 7.2.3.1) provided little evidence that long-term exposure to ambient O_3 was associated with significant deficits in the growth rate of lung function in children. The strongest evidence was for medium-term effects of extended O_3 exposures over several summer months on lung function (FEV_1) in children, *i.e.,* reduced lung function growth being associated with higher ambient O_3 levels. Short-term O_3 exposure studies presented in the ISA (U.S. EPA, 2013a, section 6.2.1.2) provide a cumulative body of epidemiologic evidence that strongly supports associations between ambient O_3 exposure and decrements in lung function among children. A later CHS study (Islam et al., 2007) included in this review (U.S. EPA, 2013a, section 7.2.3.1) also reported no substantial differences in the effect of O_3 on lung function. However, in a more recent CHS study, Breton et al. (2011) hypothesized that genetic variation in genes on the glutathione metabolic pathway may influence the association between ambient air pollutant exposures and lung function growth in children, and found that variation in the GSS locus was associated with differences in risk of children for lung function growth deficits associated ambient air pollutants, including O_3. A recent study (Rojas-Martinez et al., 2007) of long-term exposure to O_3, described in section 7.2.3.1 of the ISA (U.S. EPA, 2013a, p. 7–19), observed a relationship with pulmonary function declines in school-aged children where O_3 and other pollutant levels were higher (90 ppb at high end of the range) than those in the CHS. Two studies of adult cohorts provide mixed results where long-term exposures were at the high end of the range.

Long-term studies in animals allow for greater insight into the potential effects of prolonged exposure to O_3 that may not be easily measured in humans, such as structural changes in the respiratory tract. Despite uncertainties, epidemiologic studies observing associations of O_3 exposure with functional changes in humans can attain biological plausibility in conjunction with long-term toxicological studies, particularly O_3-inhalation studies performed in non-human primates whose respiratory systems most closely resemble that of the human. An important series of studies, discussed in section 7.2.3.2 of the ISA (U.S. EPA, 2013a), have used nonhuman primates to examine the effect of O_3 alone, or in combination with an inhaled allergen, house dust mite antigen (HDMA), on morphology and lung function. Animals exhibit the hallmarks of allergic asthma defined for humans (NHLBI, 2007). These studies and others have demonstrated changes in pulmonary function and airway morphology in adult and infant nonhuman primates repeatedly exposed to environmentally relevant concentrations of O_3 (U.S. EPA, 2013a, section 7.2.3.2).

The initial observations in adult nonhuman primates have been expanded in a series of experiments using infant rhesus monkeys repeatedly exposed to 0.5 ppm O_3 starting at 1 month of age (Plopper et al., 2007; Schelegle et al. 2003). The purpose of these studies was to determine if a cyclic regimen of O_3 inhalation would amplify the allergic responses and structural remodeling associated with allergic sensitization and inhalation in the infant rhesus monkey; they provide evidence of an O_3-induced change in airway resistance and responsiveness provides biological plausibility of long-term exposure, or repeated short-term exposures, to O_3 contributing to the effects of asthma in children.

In addition, significant structural changes in the respiratory tract development, during which conducting airways increase in diameter and length, have been observed in infant rhesus monkeys after cyclic exposure to O_3 (Fanucchi et al., 2006). These effects are noteworthy because of their potential contribution to airway obstruction and AHR which are central features of asthma. A number of studies in both non-human primates and rodents demonstrate that O_3 exposure can increase collagen synthesis and deposition, including fibrotic-like changes in the lung (U.S. EPA, 2013a, section 7.2.3.2).

Collectively, evidence from animal studies strongly suggests that chronic O_3 exposure is capable of damaging the distal airways and proximal alveoli, resulting in lung tissue remodeling and leading to apparent irreversible changes. Potentially, persistent inflammation and interstitial remodeling play an important role in the progression and development of chronic lung disease. Further discussion of the modes of action that lead to O_3-induced morphological changes can be found in section 5.3.7 of the ISA (U.S. EPA, 2013a). Discussion of mechanisms involved in lifestage susceptibility and developmental effects can be found in section 5.4.2.4 of the ISA (U.S. EPA, 2013a). The findings reported in chronic animal studies offer insight into potential biological mechanisms for the suggested association between seasonal O_3 exposure and reduced lung function development in children as observed in epidemiologic studies (U.S. EPA, 2013a, section 7.2.3.1).

iv. Respiratory Mortality

A limited number of epidemiologic studies have assessed the relationship between long-term exposure to O_3 and mortality in adults. The 2006 O_3 AQCD concluded that an insufficient amount of evidence existed ''to suggest a causal relationship between chronic O_3 exposure and increased risk for mortality in humans'' (U.S. EPA, 2006a). Though total and cardio-pulmonary mortality were considered in these studies, respiratory mortality was not specifically considered.

In the most recent follow-up analysis of the American Cancer Society (ACS) cohort (Jerrett et al., 2009), cardiopulmonary deaths were separately subdivided into respiratory and cardiovascular deaths, rather than combined as in the Pope et al. (2002) work. Increased O_3 exposure was associated with the risk of death from respiratory causes, and this effect was robust to the inclusion of $PM_{2.5}$. The association between increased O_3 concentrations and increased risk of death from respiratory causes was insensitive to the use of different models and to adjustment for several ecologic variables considered individually. The authors reported that when seasonal averages of 1-hour daily maximum O_3 concentrations ranged from 33 to 104 ppb, there was no statistical deviation from a linear concentration-response relationship between O_3 and respiratory mortality across 96 U.S. cities (U.S. EPA, 2013a, section 7.7). However, the authors also

evaluated the degree to which models incorporating thresholds provided a better fit to the data. Based on these analyses, Jerrett et al. (2009) reported ''limited evidence'' for an effect threshold at an O_3 concentration of 56 ppb (p=0.06).

Additionally, a recent multicity time series study (Zanobetti and Schwartz, 2011), which followed (from 1985 to 2006) four cohorts of Medicare enrollees with chronic conditions that might predispose to O_3-related effects, observed an association between long-term (warm season) exposure to O_3 and elevated risk of mortality in the cohort that had previously experienced an emergency hospital admission due to COPD. A key limitation of this study is the inability to control for $PM_{2.5}$, because data were not available in these cities until 1999.

c. Cardiovascular Effects

A relatively small number of studies have examined the potential effect of short-term O_3 exposure on the cardiovascular system. The 2006 O_3 AQCD (U.S. EPA, 2006a, p. 8–77) concluded that ''O_3 directly and/or indirectly contributes to cardiovascular-related morbidity,'' but added that the body of evidence was limited. This conclusion was based on a controlled human exposure study that included hypertensive adult males; a few epidemiologic studies of physiologic effects, heart rate variability, arrhythmias, myocardial infarctions, and hospital admissions; and toxicological studies of heart rate, heart rhythm, and blood pressure.

More recently, the body of scientific evidence available that has examined the effect of O_3 on the cardiovascular system has expanded. There is an emerging body of animal toxicological evidence demonstrating that short-term exposure to O_3 can lead to autonomic nervous system alterations (in heart rate and/or heart rate variability) and suggesting that proinflammatory signals may mediate cardiovascular effects. Interactions of O_3 with respiratory tract components result in secondary oxidation product formation and subsequent production of inflammatory mediators, which have the potential to penetrate the epithelial barrier and to initiate toxic effects systemically. In addition, animal toxicological studies of long-term exposure to O_3 provide evidence of enhanced atherosclerosis and ischemia/reperfusion (I/R) injury, corresponding with development of a systemic oxidative, proinflammatory environment. Recent experimental and epidemiologic studies have investigated O_3-related cardiovascular events and are summarized in section 6.3 of the ISA (U.S. EPA, 2013a). Overall, the ISA summarized the evidence in this review as follows (U.S. EPA, 2013a, p. 6–211).

> In conclusion, animal toxicological studies demonstrate O_3-induced cardiovascular effects, and support the strong body of epidemiologic evidence indicating O_3-induced cardiovascular mortality. Animal toxicological and controlled human exposure studies provide evidence for biologically plausible mechanisms underlying these O_3-induced cardiovascular effects. However, a lack of coherence with epidemiologic studies of cardiovascular morbidity remains an important uncertainty.

Controlled human exposure studies discussed in previous AQCDs have not demonstrated any consistent extrapulmonary effects. In this review, evidence from controlled human exposure studies suggests cardiovascular effects in response to short-term O_3 exposure (U.S. EPA, 2013a, section 6.3.1) and provides some coherence with evidence from animal toxicology studies. Controlled human exposure studies also support the animal toxicological studies by demonstrating O_3-induced effects on blood biomarkers of systemic inflammation and oxidative stress, as well as changes in biomarkers that can indicate the potential for increased clotting following O_3 exposures. Increases and decreases in high frequency heart rate variability (HRV) have been reported following relatively low (120 ppb during rest) and high (300 ppb with exercise) O_3 exposures, respectively. These changes in cardiac function observed in animal and human studies provide preliminary evidence for O_3-induced modulation of the autonomic nervous system through the activation of neural reflexes in the lung (U.S. EPA 2013a, section 5.3.2).

Overall, the ISA concludes that the available body of epidemiologic evidence examining the relationship between short-term exposures to O_3 concentrations and cardiovascular morbidity is inconsistent (U.S. EPA, 2013a, section 6.3.2.9). Across studies, different definitions (*i.e.,* ICD–9 diagnostic codes) were used for both all-cause and cause-specific cardiovascular morbidity (U.S. EPA, 2013a, Tables 6–35 to 6–39), which may contribute to inconsistency in results. However, within diagnostic categories, no consistent pattern of association was found with O_3. Generally, the epidemiologic studies used nearest air monitors to assess O_3 concentrations, with a few exceptions that used modeling or personal exposure monitors. The inconsistencies in the associations observed between short-term O_3 and cardiovascular disease (CVD) morbidities are unlikely to be explained by the different exposure assignment methods used (U.S. EPA, 2013a, section 4.6). The wide variety of biomarkers considered and the lack of consistency among definitions used for specific cardiovascular disease endpoints (*e.g.,* arrhythmias, HRV) make comparisons across studies difficult.

Despite the inconsistent evidence for an association between O_3 concentration and CVD morbidity, mortality studies indicate a consistent positive association between short-term O_3 exposure and cardiovascular mortality in multicity studies and in a multi-continent study. When examining mortality due to CVD, epidemiologic studies consistently observe positive associations with short-term exposure to O_3. Additionally, there is some evidence for an association between long-term exposure to O_3 and mortality, although the association between long-term ambient O_3 concentrations and cardiovascular mortality can be confounded by other pollutants (U.S. EPA, 2013a). The ISA (U.S. EPA 2013a, section 6.3.4) states that taken together, the overall body of evidence across the animal and human studies is sufficient to conclude that there is likely to be a causal relationship between relevant short-term exposures to O_3 and cardiovascular system effects.

d. Total Mortality

The 2006 O_3 AQCD concluded that the overall body of evidence was highly suggestive that short-term exposure to O_3 directly or indirectly contributes to nonaccidental and cardiopulmonary-related mortality in adults, but additional research was needed to more fully establish underlying mechanisms by which such effects occur (U.S. EPA, 2013a, p. 2–18). In building on the 2006 evidence for mortality, the ISA states the following (U.S. EPA, 2013a, p. 6–261).

> The evaluation of new multicity studies that examined the association between short-term O_3 exposures and mortality found evidence that supports the conclusions of the 2006 AQCD. These new studies reported consistent positive associations between short-term O_3 exposure and all-cause (nonaccidental) mortality, with associations persisting or increasing in magnitude during the warm season, and provide additional support for associations between O_3 exposure and cardiovascular and respiratory mortality.

The 2006 O_3 AQCD reviewed a large number of time-series studies of associations between short-term O_3 exposures and total mortality including single- and multicity studies, and meta-analyses. In the large U.S. multicity

studies that examined all-year data, effect estimates corresponding to single-day lags ranged from a 0.5–1% increase in all-cause (nonaccidental) total mortality per a 20 ppb (24-hour), 30 ppb (8-hour maximum), or 40 ppb (1-hour maximum) increase in ambient O_3 (U.S. EPA, 2013a, section 6.6.2). Available studies reported some evidence for heterogeneity in O_3 mortality risk estimates across cities and across studies. Studies that conducted seasonal analyses reported larger O_3 mortality risk estimates during the warm or summer season. Overall, the 2006 O_3 AQCD identified robust associations between various measures of daily ambient O_3 concentrations and all-cause mortality, which could not be readily explained by confounding due to time, weather, or copollutants. With regard to cause-specific mortality, consistent positive associations were reported between short-term O_3 exposure and cardiovascular mortality, with less consistent evidence for associations with respiratory mortality. The majority of the evidence for associations between O_3 and cause-specific mortality were from single-city studies, which had small daily mortality counts and subsequently limited statistical power to detect associations. The 2006 O_3 AQCD concluded that ''the overall body of evidence is highly suggestive that O_3 directly or indirectly contributes to nonaccidental and cardiopulmonary-related mortality'' (U.S. EPA, 2013a, section 6.6.1).

Recent studies have strengthened the body of evidence that supports the association between short-term O_3 concentrations and mortality in adults. This evidence includes a number of studies reporting associations with nonaccidental as well as cause-specific mortality. Multi-continent and multicity studies have consistently reported positive and statistically significant associations between short-term O_3 concentrations and all-cause mortality, with evidence for larger mortality risk estimates during the warm or summer months (U.S. EPA, 2013a, Figure 6–27; Table 6–42). Similarly, evaluations of cause-specific mortality have reported consistently positive associations with O_3, particularly in analyses restricted to the warm season (U.S. EPA, 2013a, Figure 6–37; Table 6–53).[56]

In assessing the evidence for O_3-related mortality, the 2006 AQCD also noted that multiple uncertainties remained regarding the relationship between short-term O_3 concentrations and mortality, including the extent of residual confounding by copollutants; characterization of the factors that modify the O_3-mortality association; the appropriate lag structure for identifying O_3-mortality effects; and the shape of the O_3-mortality concentration-response function and whether a threshold exists. Many of the studies, published since the last review, have attempted to address one or more of these uncertainties. The ISA (U.S. EPA, 2013a, section 6.6.2) discusses the extent to which recent studies have evaluated these uncertainties in the relationship between O_3 and mortality.

In particular, recent studies have evaluated different statistical approaches to examine the shape of the O_3-mortality concentration-response relationship and to evaluate whether a threshold exists for O_3-related mortality. In an analysis of the National Morbidity and Mortality Air Pollution Study (NMMAPS) data, Bell et al. (2006) evaluated the potential for a threshold in the O_3-mortality relationship. The authors reported positive and statistically significant associations with mortality in a variety of restricted analyses, including analyses restricted to days with 24-hour area-wide average O_3 concentrations below 60, 55, 50, 45, 40, 35, and 30 ppb. In these restricted analyses O_3 effect estimates were of similar magnitude, were statistically significant, and had similar statistical precision. In analyses restricted to days with 24-hour average O_3 concentrations below 25 ppb, the O_3 effect estimate was similar in magnitude to the effect estimates resulting from analyses with the higher cutoffs, but had somewhat lower statistical precision, with the estimate approaching statistical significance (*i.e.,* based on observation of Figure 2 in Bell et al., 2006). In analyses restricted to days with lower 24-hour average O_3 concentrations (*i.e.,* below 20 and 15 ppb), effect estimates were similar in magnitude to analyses with higher cutoffs, but with notably less statistical precision, and were not statistically significant (*i.e.,* confidence intervals included the null, indicating no O_3-associated mortality, based on observation of Figure 2 in Bell et al., 2006). Ozone was no longer positively associated with mortality when the analysis was restricted to days with 24-hour O_3 concentrations below 10 ppb. Given the relatively small number of days included in these restricted analyses, especially for cut points of 20 ppb and below,[57] statistical uncertainty is increased.

Bell et al. (2006) also evaluated the shape of the concentration-response relationship between O_3 and mortality. Although the results of this analysis suggested the lack of threshold in the O_3-mortality relationship, the ISA noted that it is difficult to interpret such a curve because: (1) There is uncertainty around the shape of the concentration-response curve at 24-hour average O_3 concentrations generally below 20 ppb; and (2) the concentration-response curve does not take into consideration the heterogeneity in O_3-mortality risk estimates across cities (U.S. EPA, 2013a, section 6.6.2.3).

Several additional studies have used the NMMAPS dataset to evaluate the concentration-response relationship between short-term O_3 concentrations and mortality. For example, using the same data as Bell et al. (2006), Smith et al. (2009) conducted a subset analysis, but instead of restricting the analysis to days with O_3 concentrations below a cutoff, the authors only included days *above* a defined cutoff (cutoffs from 15 and 60 ppb). The results of this analysis were consistent with those reported by Bell et al. (2006). Specifically, the authors reported consistent positive associations for all cutoff concentrations up to concentrations where the total number of days available were so limited that the variability around the central estimate was increased (*i.e.,* cutoff values at or above about 50 ppb) (U.S. EPA, 2013a, section 6.6.2.3). In addition, using NMMAPS data for 1987–1994 for Chicago, Pittsburgh, and El Paso, Xia and Tong (2006) reported evidence for a threshold around a 24-hour average O_3 concentration of 25 ppb, though the threshold values estimated in the analysis were sometimes in the range of where data density was low (U.S. EPA, 2013a, section 6.6.2.3). Stylianou and Nicolich (2009) examined the existence of thresholds following an approach similar to Xia and Tong (2006) using data from NMMAPS for nine major U.S. cities (*i.e.,* Baltimore, Chicago, Dallas/Fort Worth, Los Angeles, Miami, New York, Philadelphia, Pittsburgh, and Seattle) for the years 1987–2000. The authors reported that the estimated O_3-mortality risks varied across the nine cities, with the models exhibiting apparent thresholds in the 10–45 ppb range for O_3 (24-hour average). However, given the city-to-city variation in risk estimates, combining the city-specific estimates into an overall estimate complicates the interpretation of the results. Additional studies in

[56] Respiratory mortality is discussed in more detail above.

[57] For example, Bell et al. (2006) reported that for analyses restricted to 24-hour O_3 concentrations at or below 20 ppb, 73% of days were excluded on average across the 98 communities.

Europe, Canada, and Asia did not report the existence of a threshold (Katsouyanni et al., 2009), with inconsistent and/or inconclusive results across cities, or a non-linear relationship in the O_3-mortality concentration-response curve (Wong et al., 2010).

3. Adversity of O_3 Effects

In making judgments as to when various O_3-related effects become regarded as adverse to the health of individuals, in previous NAAQS reviews, the EPA has relied upon the guidelines published by the American Thoracic Society (ATS) and the advice of CASAC. In 2000, the ATS published an official statement on ''What Constitutes an Adverse Health Effect of Air Pollution?'' (ATS, 2000), which updated and built upon its earlier guidance (ATS, 1985). The earlier guidance defined adverse respiratory health effects as ''medically significant physiologic changes generally evidenced by one or more of the following: (1) Interference with the normal activity of the affected person or persons, (2) episodic respiratory illness, (3) incapacitating illness, (4) permanent respiratory injury, and/or (5) progressive respiratory dysfunction,'' while recognizing that perceptions of ''medical significance'' and ''normal activity'' may differ among physicians, lung physiologists and experimental subjects (ATS, 1985). The 2000 ATS guidance builds upon and expands the 1985 definition of adversity in several ways. The guidance concludes that transient, reversible loss of lung function in combination with respiratory symptoms should be considered adverse. There is also a more specific consideration of population risk (ATS, 2000). Exposure to air pollution that increases the risk of an adverse effect to the entire population is adverse, even though it may not increase the risk of any individual to an unacceptable level. For example, a population of asthmatics could have a distribution of lung function such that no individual has a level associated with clinically important impairment. Exposure to air pollution could shift the distribution to lower levels that still do not bring any individual to a level that is associated with clinically relevant effects. However, this would be considered to be adverse because individuals within the population would have diminished reserve function, and therefore would be at increased risk to further environmental insult (U.S. EPA, 2013a, p. lxxi; and 75 FR at 35526/2, June 22, 2010).

The ATS also concluded that elevations of biomarkers such as cell types, cytokines and reactive oxygen species may signal risk for ongoing injury and more serious effects or may simply represent transient responses, illustrating the lack of clear boundaries that separate adverse from nonadverse events. More subtle health outcomes also may be connected mechanistically to health effects that are clearly adverse, so that small changes in physiological measures may not appear clearly adverse when considered alone, but may be part of a coherent and biologically plausible chain of related health outcomes that include responses that are clearly adverse, such as mortality (U.S. EPA, 2014c, section 3.1.2.1).

In this review, the new evidence provides further support for relationships between O_3 exposures and a spectrum of health effects, including effects that meet the ATS criteria for being adverse (ATS, 1985 and 2000). The ISA determination that there is a causal relationship between short-term O_3 exposure and a full range of respiratory effects, including respiratory morbidity (*e.g.,* lung function decrements, respiratory symptoms, inflammation, hospital admissions, and emergency department visits) and mortality, provides support for concluding that short-term O_3 exposure is associated with adverse effects (U.S. EPA, 2013a, section 2.5.2). Overall, including new evidence of cardiovascular system effects, the evidence supporting an association between short-term O_3 exposures and total (nonaccidental, cardiopulmonary) respiratory mortality is stronger in this review (U.S. EPA, 2013a, section 2.5.2). And the judgment of likely causal associations between long-term measures of O_3 exposure and respiratory effects such as new-onset asthma, prevalence of asthma, asthma symptoms and control, and asthma hospital admissions provides support for concluding that long-term O_3 exposure is associated with adverse effects ranging from episodic respiratory illness to permanent respiratory injury or progressive respiratory decline (U.S. EPA, 2013a, section 7.2.8).

Application of the ATS guidelines to the least serious category of effects related to ambient O_3 exposures, which are also the most numerous and, therefore, are also potentially important from a public health perspective, involves judgments about which medical experts on CASAC panels and public commenters have in the past expressed diverse views. To help frame such judgments, in past reviews, the EPA has defined gradations of individual functional responses (*e.g.,* decrements in FEV_1 and airway responsiveness) and symptomatic responses (*e.g.,* cough, chest pain, wheeze), together with judgments as to the potential impact on individuals experiencing varying degrees of severity of these responses. These gradations were used in the 1997 O_3 NAAQS review and slightly revised in the 2008 review (U.S. EPA, 1996, p. 59; 2007, p. 3–72; 72 FR 37849, July 11, 2007). These gradations and impacts are summarized in Tables 3–2 and 3–3 in the 2007 O_3 Staff Paper (U.S. EPA, 2007, pp. 3–74 to 3–75).

For active healthy people, including children, moderate levels of functional responses (*e.g.,* FEV_1 decrements of ≥10% but <20%, lasting 4 to 24 hours) and/or moderate symptomatic responses (*e.g.,* frequent spontaneous cough, marked discomfort on exercise or deep breath, lasting 4 to 24 hours) would likely interfere with normal activity for relatively few sensitive individuals (U.S. EPA, 2007, p. 3–72; 72 FR 37849, July 11, 2007); whereas large functional responses (*e.g.,* FEV_1 decrements ≥20%, lasting longer than 24 hours) and/or severe symptomatic responses (*e.g.,* persistent uncontrollable cough, severe discomfort on exercise or deep breath, lasting longer than 24 hours) would likely interfere with normal activities for many sensitive individuals (U.S. EPA, 2007, p. 3–72; 72 FR 37849, July 11, 2007) and, therefore, would be considered adverse under ATS guidelines. For the purpose of estimating potentially adverse lung function decrements in active healthy people in the 2008 O_3 NAAQS review, the CASAC panel for that review indicated that a focus on the mid to upper end of the range of moderate levels of functional responses is most appropriate (*e.g.,* FEV_1 decrements ≥15% but <20%) (Henderson, 2006; U.S. EPA, 2007, p. 3–76). In this review, CASAC concurred that the ''[e]stimation of FEV_1 decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults'' (Frey, 2014c, p. 3). However, for children and adults with lung disease, even moderate functional (*e.g.,* FEV_1 decrements ≥10% but <20%, lasting up to 24 hours) or symptomatic responses (*e.g.,* frequent spontaneous cough, marked discomfort on exercise or with deep breath, wheeze accompanied by shortness of breath, lasting up to 24 hours) would likely interfere with normal activity for many individuals, and would likely result in additional and more frequent use of

medication (U.S. EPA, 2007, p. 3–72; 72 FR 37849, July 11, 2007). For people with lung disease, large functional responses (*e.g.,* FEV_1 decrements ≥20%, lasting longer than 24 hours) and/or severe symptomatic responses (*e.g.,* persistent uncontrollable cough, severe discomfort on exercise or deep breath, persistent wheeze accompanied by shortness of breath, lasting longer than 24 hours) would likely interfere with normal activity for most individuals and would increase the likelihood that these individuals would seek medical treatment (U.S. EPA, 2007, p. 3–72; 72 FR 37849, July 11, 2007). In the last O_3 NAAQS review, for the purpose of estimating potentially adverse lung function decrements in people with lung disease the CASAC panel indicated that a focus on the lower end of the range of moderate levels of functional responses is most appropriate (*e.g.,* FEV_1 decrements ≥10%) (Henderson, 2006; U.S. EPA, 2007, p. 3–76). In addition, in their letter advising the Administrator on the reconsideration of the 2008 final decision, CASAC stated that ''[a] 10% decrement in FEV1 can lead to respiratory symptoms, especially in individuals with pre-existing pulmonary or cardiac disease. For example, people with chronic obstructive pulmonary disease have decreased ventilatory reserve (*i.e.,* decreased baseline FEV_1) such that a ≥10% decrement could lead to moderate to severe respiratory symptoms'' (Samet, 2011). In this review, CASAC concurred that ''[a]n FEV1 decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease'' (Frey, 2014c, p. 3).

In judging the extent to which these impacts represent effects that should be regarded as adverse to the health status of individuals, in previous NAAQS reviews, the EPA has also considered whether effects were experienced repeatedly during the course of a year or only on a single occasion (U.S. EPA, 2007). Although some experts would judge single occurrences of moderate responses to be a nuisance, especially for healthy individuals, a more general consensus view of the adversity of such moderate responses emerges as the frequency of occurrence increases. Thus it has been judged that repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered to be adverse since they could well set the stage for more serious illness (61 FR 65723). The CASAC panel in the 1997 NAAQS review expressed a consensus view that these ''criteria for the determination of an adverse physiological response were reasonable'' (Wolff, 1995). In the review completed in 2008, estimates of repeated occurrences continued to be an important public health policy factor in judging the adversity of moderate lung function decrements in healthy and asthmatic people (72 FR 37850, July 11, 2007).

Evidence new to this review indicates that 6.6-hour exposures to 60 ppb O_3 during moderate exertion can result in pulmonary inflammation in healthy adults (based on study mean). As discussed in the ISA, the initiation of inflammation can be considered as evidence that injury has occurred. Inflammation induced by a single O_3 exposure can resolve entirely but, as noted in the ISA (U.S. EPA, 2013a, p. 6–76), ''continued acute inflammation can evolve into a chronic inflammatory state,'' which would be adverse.

Responses measured in controlled human exposure studies indicate that the range of effects elicited in humans exposed to ambient O_3 concentrations include: Decreased inspiratory capacity; mild bronchoconstriction; rapid, shallow breathing pattern during exercise; and symptoms of cough and pain on deep inspiration (U.S. EPA, 2013a, section 6.2.1.1). Young, healthy adults exposed for 6.6 hours to O_3 concentrations ≥60 ppb, while engaged in intermittent moderate exertion, develop reversible, transient decrements in lung function. In addition, depending on the exposure concentration and the duration of exposure, young healthy adults have been shown to experience symptoms of breathing discomfort and inflammation if minute ventilation or duration of exposure is increased sufficiently (U.S. EPA, 2013a, section 6.2.1.1). Among healthy subjects there is considerable interindividual variability in the magnitude of the FEV_1 responses, but when data were combined across studies at 60 ppb (U.S. EPA, 2013a, pp. 6–17 to 6–18), 10% of healthy subjects had >10% FEV_1 decrements. Moreover, consistent with the findings of the ISA (U.S. EPA, 2013a, section 6.2.1.1), CASAC concluded that ''[a]sthmatic subjects appear to be at least as sensitive, if not more sensitive, than non-asthmatic subjects in manifesting ozone-induced pulmonary function decrements'' (Frey, 2014c, p. 4). The combination of lung function decrements and respiratory symptoms, which has been considered adverse in previous reviews, has been demonstrated in healthy adults following prolonged (6.6 hour) exposures, while at intermittent moderate exertion, to 72 ppb. For these types of effects, information from controlled human exposure studies, which provides an indication of the magnitude and thus adversity of effects at different O_3 concentrations, combined with estimates of occurrences in the population from the HREA, provide information about their importance from a policy perspective.

4. Ozone-Related Impacts on Public Health

Setting standards to provide appropriate public health protection requires consideration of the factors that put populations at greater risk from O_3 exposure. In order to estimate the potential for public health impacts, it is important to consider not only the adversity of the health effects, but also the populations at greater risk and potential behaviors that may reduce exposures.

a. Identification of At-Risk Populations and Lifestages

The currently available evidence expands the understanding of populations that were identified to be at greater risk of O_3-related health effects at the time of the last review (*i.e.,* people who are active outdoors, people with lung disease, children and older adults and people with increased responsiveness to O_3) and supports the identification of additional factors that may lead to increased risk (U.S. EPA, 2006, section 3.6.2; U.S. EPA, 2013a, Chapter 8). Populations and lifestages may be at greater risk for O_3-related health effects due to factors that contribute to their susceptibility and/or vulnerability to O_3. The definitions of susceptibility and vulnerability have been found to vary across studies, but in most instances ''susceptibility'' refers to biological or intrinsic factors (*e.g.,* lifestage, sex, preexisting disease/conditions) while ''vulnerability'' refers to non-biological or extrinsic factors (*e.g.,* socioeconomic status [SES]) (U.S. EPA, 2013a, p. 8–1; U.S. EPA, 2010c, 2009d). In some cases, the terms ''at-risk'' and ''sensitive'' have been used to encompass these concepts more generally. In the ISA and PA, ''at-risk'' is the all-encompassing term used to define groups with specific factors that increase their risk of O_3-related health effects.

There are multiple avenues by which groups may experience increased risk for O_3-induced health effects. A population or lifestage [58] may exhibit greater effects than other populations or lifestages exposed to the same

[58] Lifestages, which in this case includes childhood and older adulthood, are experienced by most people over the course of a lifetime, unlike other factors associated with at-risk populations.

concentration or dose, or they may be at greater risk due to increased exposure to an air pollutant (*e.g.,* time spent outdoors). A group with intrinsically increased risk would have some factor(s) that increases risk through a biological mechanism and, in general, would have a steeper concentration-risk relationship, compared to those not in the group. Factors that are often considered intrinsic include pre-existing asthma, genetic background, and lifestage. A group of people could also have extrinsically increased risk, which would be through an external, non-biological factor, such as socioeconomic status (SES) and diet. Some groups are at risk of increased internal dose at a given exposure concentration, for example, because of breathing patterns. This category would include people who work or exercise outdoors. Finally, there are those who might be placed at increased risk for experiencing greater exposures by being exposed to higher O_3 concentrations. This would include, for example, groups of people with greater exposure to ambient O_3 due to less availability or use of home air conditioners such that they are more likely to be in locations with open windows on high O_3 days. Some groups may be at increased risk of O_3-related health effects through a combination of factors. For example, children tend to spend more time outdoors when O_3 levels are high, and at higher levels of activity than adults, which leads to increased exposure and dose, and they also have biological, or intrinsic, risk factors (*e.g.,* their lungs are still developing) (U.S. EPA, 2013a, Chapter 8). An at-risk population or lifestage is more likely to experience adverse health effects related to O_3 exposures and/or, develop more severe effects from exposure than the general population.

i. People With Specific Genetic Variants

There is adequate evidence for populations with certain genotypes being more at-risk than others to the effects of O_3 exposure on health (U.S. EPA, 2013a, section 8.1). Controlled human exposure and epidemiologic studies have reported evidence of O_3-related increases in respiratory symptoms or decreases in lung function with variants including GSTM1, GSTP1, HMOX1, and NQO1. NQO1 deficient mice were found to be resistant to O_3-induced AHR and inflammation, providing biological plausibility for results of studies in humans. Additionally, studies of rodents have identified a number of other genes that may affect O_3-related health outcomes, including genes related to innate immune signaling and pro- and anti-inflammatory genes, which have not been investigated in human studies.

ii. People With Asthma

Previous O_3 AQCDs identified individuals with asthma as a population at increased risk of O_3-related health effects. Multiple new epidemiologic studies included in the ISA have evaluated the potential for increased risk of O_3-related health effects in people with asthma, including: Lung function; symptoms; medication use; AHR; and airway inflammation (also measured as exhaled nitric oxide fraction, or FeNO). A study of lifeguards in Texas reported decreased lung function with short-term O_3 exposure among both individuals with and without asthma; however, the decrease was greater among those with asthma (Thaller et al., 2008). A Mexican study of children ages 6–14 detected an association between short-term O_3 exposure and wheeze, cough, and bronchodilator use among asthmatics but not non-asthmatics, although this may have been the result of a small non-asthmatic population (Escamilla-Nuñez et al., 2008). A study of modification by AHR (an obligate condition among asthmatics) reported greater short-term O_3-associated decreases in lung function in elderly individuals with AHR, especially among those who were obese (Alexeeff et al., 2007). With respect to airway inflammation, in one study, a positive association was reported for airway inflammation among asthmatic children following short-term O_3 exposure, but the observed association was similar in magnitude to that of non-asthmatics (Barraza-Villarreal et al., 2008). Similarly, another study of children in California reported an association between O_3 concentration and FeNO that persisted both among children with and without asthma as well as those with and without respiratory allergy (Berhane et al., 2011). Finally, Khatri et al. (2009) found no association between short-term O_3 exposure and altered lung function for either asthmatic or non-asthmatic adults, but did note a decrease in lung function among individuals with allergies.

New evidence for difference in effects among asthmatics has been observed in studies that examined the association between O_3 exposure and altered lung function by asthma medication use. A study of children with asthma living in Detroit reported a greater association between short-term O_3 and lung function (*i.e.,* FEV_1) for corticosteroid users compared with noncorticosteroid users (Lewis et al., 2005). Conversely, another study found decreased lung function among noncorticosteroid users compared to users, although in this study, a large proportion of non-users were considered to be persistent asthmatics (Hernández-Cadena et al., 2009). Lung function was not related to short-term O_3 exposure among corticosteroid users and non-users in a study taking place during the winter months in Canada (Liu et al., 2009). Additionally, a study of airway inflammation reported a counterintuitive inverse association with O_3 of similar magnitude for all groups of corticosteroid users and non-users (Qian et al., 2009).

Controlled human exposure studies that have examined the effects of O_3 on adults with asthma and healthy controls are limited. Based on studies reviewed in the 1996 and 2006 O_3 AQCDs, subjects with asthma appeared to be more sensitive to acute effects of O_3 in terms of FEV_1 and inflammatory responses than healthy non-asthmatic subjects. For instance, Horstman et al. (1995) observed that mild-to-moderate asthmatics, on average, experienced double the O_3-induced FEV_1 decrement of healthy subjects (19% versus 10%, respectively, p=0.04). Moreover, a statistically significant positive correlation between FEV_1 responses to O_3 exposure and baseline lung function was observed in individuals with asthma, *i.e.,* responses increased with severity of disease. Minimal evidence exists suggesting that individuals with asthma have smaller O_3-induced FEV_1 decrements than healthy subjects (3% versus 8%, respectively) (Mudway et al., 2001). However, the asthmatics in that study also tended to be older than the healthy subjects, which could partially explain their lesser response since FEV_1 responses to O_3 exposure diminish with age. Individuals with asthma also had significantly more neutrophils in the BALF (18 hours postexposure) than similarly exposed healthy individuals (Peden et al., 1997; Scannell et al., 1996; Basha et al., 1994). Furthermore, a study examining the effects of O_3 on individuals with atopic asthma and healthy controls reported that greater numbers of neutrophils, higher levels of cytokines and hyaluronan, and greater expression of macrophage cell-surface markers were observed in induced sputum of atopic asthmatics compared with healthy controls (Hernandez et al., 2010). Differences in O_3-induced epithelial cytokine expression were noted in bronchial biopsy samples from asthmatics and healthy controls (Bosson et al., 2003). Cell-surface marker and cytokine expression results, and the

presence of hyaluronan, are consistent with O_3 having greater effects on innate and adaptive immunity in these asthmatic individuals. In addition, studies have demonstrated that O_3 exposure leads to increased bronchial reactivity to inhaled allergens in mild allergic asthmatics (Kehrl et al., 1999; Jorres et al., 1996) and to the influx of eosinophils in individuals with pre-existing allergic disease (Vagaggini et al., 2002; Peden et al., 1995). Taken together, these results point to several mechanistic pathways which could account for the enhanced sensitivity to O_3 in subjects with asthma (U.S. EPA, 2013a, section 5.4.2.2).

As noted in the previous review (72 FR 37846, July 11, 2007) asthmatics present a differential response profile for cellular, molecular, and biochemical parameters (U.S. EPA, 2006a, Figure 8–1) that are altered in response to acute O_3 exposure. Ozone-induced increases in neutrophils, IL–8 and protein were found to be significantly higher in the BAL fluid from asthmatics compared to healthy subjects, suggesting mechanisms for the increased sensitivity of asthmatics (Basha et al., 1994; McBride et al., 1994; Scannell et al., 1996; Hiltermann et al., 1999; Holz et al., 1999; Bosson et al., 2003). Neutrophils, or PMNs, are the white blood cell most associated with inflammation. IL–8 is an inflammatory cytokine with a number of biological effects, primarily on neutrophils. The major role of this cytokine is to attract and activate neutrophils. Protein in the airways is leaked from the circulatory system, and is a marker for increased cellular permeability.

Bronchial constriction following provocation with O_3 and/or allergens presents a two-phase response. The early response is mediated by release of histamine and leukotrienes that leads to contraction of smooth muscle cells in the bronchi, narrowing the lumen and decreasing the airflow. In people with allergic airway disease, including people with rhinitis and asthma, these mediators also cause accumulation of eosinophils in the airways (Bascom et al., 1990; Jorres et al., 1996; Peden et al., 1995 and 1997; Frampton et al., 1997a; Michelson et al., 1999; Hiltermann et al., 1999; Holz et al., 2002; Vagaggini et al., 2002). In asthma, the eosinophil, which increases inflammation and allergic responses, is the cell most frequently associated with exacerbations of the disease. A study by Bosson et al. (2003) evaluated the difference in O_3-induced bronchial epithelial cytokine expression between healthy and asthmatic subjects. After O_3 exposure the epithelial expression of IL–5 and GM–CSF increased significantly in asthmatics, compared to healthy subjects. Asthma is associated with Th2-related airway response (allergic response), and IL–5 is an important Th2-related cytokine. The O_3-induced increase in IL–5, and also in GM–CSF, which affects the growth, activation and survival of eosinophils, may indicate an effect on the Th2-related airway response and on airway eosinophils. The authors reported that the O_3-induced Th2-related cytokine responses that were found within the asthmatic group may indicate a worsening of their asthmatic airway inflammation and thus suggest a plausible link to epidemiological data indicating O_3-associated increases in bronchial reactivity and hospital admissions.

The accumulation of eosinophils in the airways of asthmatics is followed by production of mucus and a late-phase bronchial constriction and reduced airflow. In a study of 16 intermittent asthmatics, Hiltermann et al. (1999) found that there was a significant inverse correlation between the O_3-induced change in the percentage of eosinophils in induced sputum and the change in PC20, the concentration of methacholine causing a 20% decrease in FEV_1. Characteristic O_3-induced inflammatory airway neutrophilia at one time was considered a leading mechanism of airway hyperresponsiveness. However, Hiltermann et al. (1999) determined that the O_3-induced change in percentage neutrophils in sputum was not significantly related to the change in PC20. These results are consistent with the results of Zhang et al. (1995), which found neutrophilia in a murine model to be only coincidentally associated with airway hyperresponsiveness, *i.e.,* there was no cause and effect relationship (U.S. EPA, 2006a, AX 6–26). Hiltermann et al. (1999) concluded that the results point to the role of eosinophils in O_3-induced airway hyperresponsiveness. Increases in O_3-induced nonspecific airway responsiveness incidence and duration could have important clinical implications for asthmatics.

Toxicological studies provide additional evidence of the biological basis for the greater effects of O_3 among those with asthma or AHR (U.S. EPA, 2013a, section 8.2.2). In animal toxicological studies, an asthmatic phenotype is modeled by allergic sensitization of the respiratory tract. Many of the studies that provide evidence that O_3 exposure is an inducer of AHR and remodeling utilize these types of animal models. For example, a series of experiments in infant rhesus monkeys have shown these effects, but only in monkeys sensitized to house dust mite allergen. Similarly, adverse changes in pulmonary function were demonstrated in mice exposed to O_3; enhanced inflammatory responses were in rats exposed to O_3, but only in animals sensitized to allergen. In general, it is the combined effects of O_3 and allergic sensitization which result in measurable effects on pulmonary function. In a pulmonary fibrosis model, exposure to O_3 for 5 days increased pulmonary inflammation and fibrosis, along with the frequency of bronchopneumonia in rats. Thus, short-term exposure to O_3 may enhance damage in a previously injured lung (U.S. EPA, 2013a, section 8.2.2).

In the 2006 O_3 AQCD, the potential for individuals with asthma to have greater risk of O_3-related health effects was supported by a number of controlled human exposure studies, evidence from toxicological studies, and a limited number of epidemiologic studies. In section 8.2.2, the ISA reports that in the recent epidemiologic literature some, but not all, studies report greater risk of health effects among individuals with asthma. Studies examining effect measure modification of the relationship between short-term O_3 exposure and altered lung function by corticosteroid use provided limited evidence of O_3-related health effects. However, recent studies of behavioral responses have found that studies do not take into account individual behavioral adaptations to forecasted air pollution levels (such as avoidance and reduced time outdoors), which may underestimate the observed associations in studies that examined the effect of O_3 exposure on respiratory health (Neidell and Kinney, 2010). This could explain some inconsistency observed among recent epidemiologic studies. The evidence from controlled human exposure studies provides support for increased detriments in FEV_1 and greater inflammatory responses to O_3 in individuals with asthma than in healthy individuals without a history of asthma. The collective evidence for increased risk of O_3-related health effects among individuals with asthma from controlled human exposure studies is supported by recent toxicological studies which provide biological plausibility for heightened risk of asthmatics to respiratory effects due to O_3 exposure. Overall, the ISA finds there is adequate evidence for asthmatics to be an at-risk population.

iii. Children

Children are considered to be at greater risk from O_3 exposure because their respiratory systems undergo lung

growth until about 18–20 years of age and are therefore thought to be intrinsically more at risk for O_3-induced damage (U.S. EPA, 2006a). It is generally recognized that children spend more time outdoors than adults, and, therefore, would be expected to have higher exposure to O_3 than adults. Children aged 11 years and older and adults have higher absolute ventilation rates than younger children aged 1–11 years. However, younger children have higher ventilation rates relative to their lung volumes, which tends to increase dose normalized to lung surface area. In all ages, exercise intensity has a substantial effect on ventilation rate, high intensity activity results in nearly double the ventilation rate for moderate activity. For more information on time spent outdoors and ventilation rate differences by age group, see section 4.4.1 in the ISA (U.S. EPA, 2013a).

The 1996 O_3 AQCD reported clinical evidence that children, adolescents, and young adults (<18 years of age) appear, on average, to have nearly equivalent spirometric responses to O_3 exposure, but have greater responses than middle-aged and older adults (U.S. EPA, 1996). Symptomatic responses (*e.g.,* cough, shortness of breath, pain on deep inspiration) to O_3 exposure, however, appear to increase with age until early adulthood and then gradually decrease with increasing age (U.S. EPA, 1996). Complete lung growth and development is not achieved until 18–20 years of age in women and the early 20s for men; pulmonary function is at its maximum during this time as well.

Recent epidemiologic studies have examined different age groups and their risk to O_3-related respiratory hospital admissions and emergency department visits. Evidence for greater risk in children was reported in several studies. A study in Cyprus of short-term O_3 concentrations and respiratory hospital admissions detected possible effect measure modification by age with a larger association among individuals <15 years of age compared with those >15 years of age; the effect was apparent only with a 2-day lag (Middleton et al., 2008). Similarly, a Canadian study of asthma-related emergency department visits reported the strongest O_3-related associations among 5- to 14-year olds compared to the other age groups (ages examined 0–75+) (Villeneuve et al., 2007). Greater O_3-associated risk in asthma-related emergency department visits were also reported among children (<15 years) as compared to adults (15 to 64 years) in a study from Finland (Halonen et al., 2009). A study of New York City hospital admissions demonstrated an increase in the association between O_3 exposure and asthma-related hospital admissions for 6- to 18-year olds compared to those <6 years old and those >18 years old (Silverman and Ito, 2010). When examining long-term O_3 exposure and asthma-related hospital admissions among children, associations were determined to be larger among children 1 to 2 years old compared to children 2 to 6 years old (Lin et al., 2008). A few studies reported positive associations among both children and adults and no modification of the effect by age.

The evidence reported in epidemiologic studies is supported by recent toxicological studies which observed O_3-induced health effects in immature animals. Early life exposures of multiple species of laboratory animals, including infant monkeys, resulted in changes in conducting airways at the cellular, functional, ultra-structural, and morphological levels. The studies conducted on infant monkeys are most relevant for assessing effects in children. Carey et al. (2007) conducted a study of O_3 exposure in infant rhesus macaques, whose respiratory tract closely resemble that of humans. Monkeys were exposed either acutely or in episodes designed to mimic human exposure. All monkeys acutely exposed to O_3 had moderate to marked necrotizing rhinitis, with focal regions of epithelial exfoliation, numerous infiltrating neutrophils, and some eosinophils. The distribution, character, and severity of lesions in episodically exposed infant monkeys were similar to that of acutely exposed animals. Neither exposure protocol for the infant monkeys produced mucous cell metaplasia proximal to the lesions, an adaptation observed in adult monkeys exposed in another study (Harkema et al., 1987). Functional and cellular changes in conducting airways were common manifestations of exposure to O_3 among both the adult and infant monkeys (Plopper et al., 2007). In addition, the lung growth of the distal conducting airways in the infant monkeys was significantly stunted by O_3 and this aberrant development was persistent 6 months postexposure (Fanucchi et al., 2006).

Age may also affect the inflammatory response to O_3 exposure. Toxicological studies reported that the difference in effects among younger lifestage test animals may be due to age-related changes in antioxidants levels and sensitivity to oxidative stress. Further discussion of these studies may be found in section 8.3.1.1 of the ISA (U.S. EPA, 2013a, p. 8–18).

The previous and recent human clinical and toxicological studies reported evidence of increased risk from O_3 exposure for younger ages, which provides coherence and biological plausibility for the findings from epidemiologic studies. Although there was some inconsistency, generally, the epidemiologic studies reported positive associations among both children and adults or just among children. The interpretation of these studies is limited by the lack of consistency in comparison age groups and outcomes examined. However, overall, the epidemiologic, controlled human exposure, and toxicological studies provide adequate evidence that children are potentially at increased risk of O_3-related health effects.

iv. Older adults

The ISA notes that older adults are at greater risk of health effects associated with O_3 exposure through a variety of intrinsic pathways (U.S. EPA, 2013a, section 8.3.1.2). In addition, older adults may differ in their exposure and internal dose. Older adults were outdoors for a slightly longer proportion of the day than adults aged 18–64 years. For more information on time spent outdoors by age group, see Section 4.4 in the ISA (U.S. EPA, 2013a). The gradual decline in physiological processes that occurs with aging may lead to increased risk of O_3-related health effects (U.S. EPA, 2006a). Respiratory symptom responses to O_3 exposure appears to increase with age until early adulthood and then gradually decrease with increasing age (U.S. EPA, 1996); lung function responses to O_3 exposure also decline from early adulthood (U.S. EPA, 1996). The reductions of these responses with age may put older adults at increased risk for continued O_3 exposure. In addition, older adults, in general, have a higher prevalence of preexisting diseases compared to younger age groups and this may also lead to increased risk of O_3-related health effects (U.S. EPA, 2013a, section 8.3.1.2). With the number of older Americans increasing in upcoming years (estimated to increase from 12.4% of the U.S. population to 19.7% between 2000 to 2030, which is approximately 35 million and 71.5 million individuals, respectively) this group represents a large population potentially at risk of O_3-related health effects (SSDAN CensusScope, 2010a; U.S. Census Bureau, 2010).

The majority of recent studies reported greater effects of short-term O_3 exposure and mortality among older adults, which is consistent with the findings of the 2006 O_3 AQCD. A study (Medina-Ramón and Schwartz, 2008)

conducted in 48 cities across the U.S. reported larger effects among adults ≥65 years old compared to those <65 years. Further investigation of this study population revealed a trend of O_3-related mortality risk that gets larger with increasing age starting at age 51 (Zanobetti and Schwartz, 2008a). Another study conducted in 7 urban centers in Chile reported similar results, with greater effects in adults ≥65 years old (Cakmak et al., 2007). More recently, a study conducted in the same area reported similar associations between O_3 exposure and mortality in adults aged <64 years old and 65 to 74 years old, but the risk was increased among the older age group (Cakmak et al., 2011). A study performed in China reported greater effects in populations ≥45 years old (compared to 5 to 44 year olds), with statistically significant effects present only among those ≥65 years old (Kan et al., 2008). An Italian study reported higher risk of all-cause mortality associated with increased O_3 concentrations among individuals ≥85 year old as compared to those 35 to 84 years old (Stafoggia et al., 2010). The Air Pollution and Health: A European and North American Approach (APHENA) project examined the association between O_3 exposure and mortality for those <75 and ≥75 years of age. In Canada, the associations for all-cause and cardiovascular mortality were greater among those ≥75 years old. In the U.S., the association for all-cause mortality was slightly greater for those <75 years of age compared to those ≥75 years old in summer-only analyses. No consistent pattern was observed for CVD mortality. In Europe, slightly larger associations for all-cause mortality were observed in those <75 years old in all-year and summer-only analyses. Larger associations were reported among those <75years for CVD mortality in all-year analyses, but the reverse was true for summer-only analyses (Katsouyanni et al., 2009).

With respect to epidemiologic studies of O_3 exposure and hospital admissions, a positive association was reported between short-term O_3 exposure and respiratory hospital admissions for adults ≥65 years old but not for those adults aged 15 to 64 years (Halonen et al., 2009). In the same study, no association was observed between O_3 concentration and respiratory mortality among those ≥65 years old or those 15 to 64 years old. No modification by age (40 to 64 year olds versus >64 year olds) was observed in a study from Brazil examining O_3 levels and COPD-related emergency department visits.

Although some outcomes reported mixed findings regarding an increase in risk for older adults, recent epidemiologic studies report consistent positive associations between short-term O_3 exposure and mortality in older adults. The evidence from mortality studies is consistent with the results reported in the 2006 O_3 AQCD and is supported by toxicological studies providing biological plausibility for increased risk of effects in older adults. Also, older adults may be experiencing increased exposure compared to younger adults. Overall, the ISA (U.S. EPA, 2013a) concludes adequate evidence is available indicating that older adults are at increased risk of O_3-related health effects.

v. People With Diets Lower in Vitamins C and E

Diet was not examined as a factor potentially affecting risk in previous O_3 AQCDs, but recent studies have examined modification of the association between O_3 and health effects by dietary factors. Because O_3 mediates some of its toxic effects through oxidative stress, the antioxidant status of an individual is an important factor that may contribute to increased risk of O_3-related health effects. Supplementation with vitamins C and E has been investigated in a number of studies as a means of inhibiting O_3-mediated damage.

Two epidemiologic studies have examined effect modification by diet and found evidence that certain dietary components are related to the effect O_3 has on respiratory outcomes. In one recent study, the effects of fruit/vegetable intake and Mediterranean diet were examined. Increases in these food patterns, which have been noted for their high vitamins C and E and omega-3 fatty acid content, were positively related to lung function in asthmatic children living in Mexico City, and modified by O_3 exposure (Romieu et al., 2009). Another study examined supplementation of the diets of asthmatic children in Mexico with vitamins C and E (Sienra-Monge et al., 2004). Associations were detected between short-term O_3 exposure and nasal airway inflammation among children in the placebo group but not in those receiving the supplementation.

The epidemiologic evidence is supported by controlled human exposure studies, discussed in section 8.4.1 of the ISA (U.S. EPA, 2013a), that have shown that the first line of defense against oxidative stress is antioxidants-rich extracellular lining fluid (ELF) which scavenges free radicals and limit lipid peroxidation. Exposure to O_3 depletes antioxidant levels in nasal ELF probably due to scrubbing of O_3; however, the concentration and the activity of antioxidant enzymes either in ELF or plasma do not appear to be related to O_3 responsiveness. Controlled studies of dietary antioxidant supplementation have demonstrated some protective effects of α-tocopherol (a form of vitamin E) and ascorbate (vitamin C) on spirometric measures of lung function after O_3 exposure but not on the intensity of subjective symptoms and inflammatory responses. Dietary antioxidants have also afforded partial protection to asthmatics by attenuating postexposure bronchial hyperresponsiveness. Toxicological studies discussed in section 8.4.1 of the ISA (U.S. EPA, 2013a) provide evidence of biological plausibility to the epidemiologic and controlled human exposure studies.

Overall, the ISA (U.S. EPA, 2013a) concludes adequate evidence is available indicating that individuals with diets lower in vitamins C and E are at risk for O_3-related health effects. The evidence from epidemiologic studies is supported by controlled human exposure and toxicological studies.

vi. Outdoor Workers

Studies included in the 2006 O_3 AQCD reported that individuals who participate in outdoor activities or work outside to be a population at increased risk based on consistently reported associations between O_3 exposure and respiratory health outcomes in these groups (U.S. EPA, 2006a). Outdoor workers are exposed to ambient O_3 concentrations for a greater period of time than individuals who spend their days indoors. As discussed in section 4.7 of the ISA (U.S. EPA, 2013a) outdoor workers sampled during the work shift had a higher ratio of personal exposure to fixed-site monitor concentrations than health clinic workers who spent most of their time indoors. Additionally, an increase in dose to the lower airways is possible during outdoor exercise due to both increases in the amount of air breathed (*i.e.,* minute ventilation) and a shift from nasal to oronasal breathing. The association between FEV_1 responses to O_3 exposure and minute ventilation is discussed more fully in section 6.2.3.1 of the 2006 O_3 AQCD (U.S. EPA, 2006a).

Previous studies have shown that increased exposure to O_3 due to outdoor work leads to increased risk of O_3-related health effects, specifically decrements in lung function (U.S. EPA, 2006a). The strong evidence from the 2006 O_3 AQCD, which demonstrated increased exposure, dose, and ultimately risk of O_3-related health effects in this population, supports the

conclusion that there is adequate evidence to indicate that increased exposure to O_3 through outdoor work increases the risk of O_3-related health effects.

In some cases, it is difficult to determine a factor that results in increased risk of effects. For example, previous assessments have included controlled human exposure studies in which some healthy individuals demonstrate greater O_3-related health effects compared to other healthy individuals. Interindividual variability has been observed for lung function decrements, symptomatic responses, pulmonary inflammation, AHR, and altered epithelial permeability in healthy adults exposed to O_3, and these results tend to be reproducible within a given individual over a period of several months indicating differences in the intrinsic responsiveness. In many cases the reasons for the variability is not clear. This may be because one or some of the factors described above have not been evaluated in studies, or it may be that additional, unidentified factors influence individual responses to O_3 (U.S. EPA, 2013a, section 8.5).

As discussed in chapter 8 of the ISA (U.S. EPA, 2013a), there is a lack of information regarding the extent to which some factors may increase risk from O_3 exposures. Due to this lack of information, the ISA concluded that for some factors, such as sex, SES, and obesity, there is only ''suggestive'' evidence of increased risk, or that for a number of factors the evidence is inadequate to draw conclusions about potential increase in risk of effects. Overall, the factors for which the ISA concludes there is adequate evidence of increased risk for experiencing O_3-related effects were related to asthma, lifestage (children and older adults), genetic variability, dietary factors, and working outdoors.

b. Size of At-Risk Populations

One consideration in the assessment of potential public health impacts is the size of various population groups for which there is adequate evidence of increased risk for health effects associated with O_3-related air pollution exposure (U.S. EPA, 2014c, section 3.1.5.2). The factors for which the ISA judged the evidence to be ''adequate'' with respect to contributing to increased risk of O_3-related effects among various populations and lifestages included: asthma; childhood and older adulthood; diets lower in vitamins C and E; certain genetic variants; and working outdoors (U.S. EPA, 2013a, section 8.5). No statistics are available to estimate the size of an at-risk population based on nutritional status or genetic variability.

With regard to asthma, Table 3–7 in the PA (U.S. EPA, 2014c, section 3.1.5.2) summarizes information on the prevalence of current asthma by age in the U.S. adult population in 2010 (Schiller et al. 2012; children—Bloom et al., 2011). Individuals with current asthma constitute a fairly large proportion of the population, including more than 25 million people. Asthma prevalence tends to be higher in children than adults. Within the U.S., approximately 8.2% of adults have reported currently having asthma (Schiller et al., 2012) and 9.5% of children have reported currently having asthma (Bloom et al., 2011).[59]

With regard to lifestages, based on U.S. census data from 2010 (Howden and Meyer, 2011), about 74 million people, or 24% of the U.S. population, are under 18 years of age and more than 40 million people, or about 13% of the U.S. population, are 65 years of age or older. Hence, a large proportion of the U.S. population (*i.e.,* more than a third) is included in age groups that are considered likely to be at increased risk for health effects from ambient O_3 exposure.

With regard to outdoor workers, in 2010, approximately 11.7% of the total number of people (143 million people) employed, or about 16.8 million people, worked outdoors one or more days per week (based on worker surveys).[60] Of these, approximately 7.4% of the workforce, or about 7.8 million people, worked outdoors three or more days per week.

The health statistics data illustrate what is known as the ''pyramid'' of effects. At the top of the pyramid, there are approximately 2.5 million deaths from all causes per year in the U.S. population, with about 250 thousand respiratory-related deaths (CDC–WONDER, 2008). For respiratory health diseases, there are nearly 3.3 million hospital discharges per year (HCUP, 2007), 8.7 million respiratory emergency department visits (HCUP, 2007), 112 million ambulatory care visits (Woodwell and Cherry, 2004), and an estimated 700 million restricted activity days per year due to respiratory conditions (Adams et al., 1999). Combining small risk estimates with relatively large baseline levels of health outcomes can result in quite large public health impacts. Thus, even a small percentage reduction in O_3 health impacts on cardiopulmonary diseases would reflect a large number of avoided cases.

c. Impacts of Averting Behavior

The activity pattern of individuals is an important determinant of their exposure (U.S. EPA, 2013a, section 4.4.1). Variation in O_3 concentrations among various microenvironments means that the amount of time spent in each location, as well as the level of activity, will influence an individual's exposure to ambient O_3. Activity patterns vary both among and within individuals, resulting in corresponding variations in exposure across a population and over time. Individuals can reduce their exposure to O_3 by altering their behaviors, such as by staying indoors, being active outdoors when air quality is better, and by reducing their activity levels or reducing the time being active outdoors on high-O_3 days (U.S. EPA, 2013a, section 4.4.2).

The widely reported Air Quality Index (AQI) conveys advice to the public, and particularly at-risk populations, on reducing short- or prolonged-exposures on days when ambient levels of common, criteria air pollutants (except lead), are elevated (*www.airnow.gov*). Information communicated by the AQI is based on the evidence and exposure/risk information assessed in the review of the NAAQS; it is updated and revised as necessary during the review of each standard. Proposed changes to the AQI sub-index for O_3, based on evidence and exposure/risk information assessed in this review, are discussed in section III below.

The AQI describes the potential for health effects from O_3 (and other individual pollutants) in six color-coded categories of air-quality, ranging from Good (green), Moderate (yellow), Unhealthy for Sensitive Groups (orange), Unhealthy (red), and Very Unhealthy (purple), and Hazardous (maroon). Levels in the unhealthy ranges (*i.e.,* Unhealthy for Sensitive Groups and above) come with recommendations about reducing exposure. Forecasted and actual AQI values for O_3 are reported to the public

[59] As noted below (II.C.3.a.ii), asthmatics can experience larger O_3-induced respiratory effects than non-asthmatic, healthy adults. The responsiveness of asthmatics to O_3 exposures could depend on factors that have not been well-evaluated such as asthma severity, the effectiveness of asthma control, or the prevalence of medication use.

[60] The O*NET program is the nation's primary source of occupational information. Central to the project is the O*NET database, containing information on hundreds of standardized and occupation-specific descriptors. The database, which is available to the public at no cost, is continually updated by surveying a broad range of workers from each occupation. *http://www.onetcenter.org/overview.html. http://www.onetonline.org/find/descriptor/browse/Work_Context/4.C.2/.*

during the O_3 season. The AQI advisories explicitly state that children, older adults, people with lung disease, and people who are active outdoors, may be at greater risk from exposure to O_3. People are advised to reduce exposure depending on the predicted O_3 levels and the likelihood of risk. This advice includes being active outdoors when air quality is better, and reducing activity levels or reducing the time being active outdoors on high-O_3 days. Staying indoors to reduce exposure is not recommended until air quality reaches the Very Unhealthy or Hazardous categories.

Evidence of individual averting behaviors in response to AQI advisories has been found in several studies, including activity pattern and epidemiologic studies, especially for the at-risk populations, such as children, older adults, and people with asthma, who are targeted by the advisories. Such effects are less pronounced in the general population, possibly due to the opportunity cost of behavior modification. Epidemiologic evidence from a study (Neidell and Kinney, 2010) conducted in the 1990's in Los Angeles, CA reports increased asthma hospital admissions among children and older adults when O_3 alert days (1-hour max O_3 concentration >200 ppb) were excluded from the analysis of daily hospital admissions and O_3 concentrations (presumably thereby eliminating averting behavior based on high O_3 forecasts). If averting behavior reduces exposure to ambient O_3, then epidemiologic studies that do not account for averting behavior may produce effect estimates that are biased toward the null due to exposure misclassification (U.S. EPA, 2013, section 4.6.6).

C. Human Exposure and Health Risk Assessments

To put judgments about health effects that are adverse for individuals into a broader public health context, the EPA has developed and applied models to estimate human exposures to O_3 and O_3-associated health risks. Exposure and risk estimates based on such models are presented and assessed in the HREA (U.S. EPA, 2014a). In reviewing the draft HREA, CASAC expressed the view that the document is ''well-written, founded based upon comprehensive analyses and adequate for its intended purpose'' (Frey, 2014a, p. 1). Analyses in the HREA inform consideration of the O_3 exposures and health risks that could be allowed by the current standard and alternative standards, and consideration of the kind and degree of uncertainties inherent in estimates of O_3 exposures and health risks.

The following sections discuss the air quality adjustment approach used in the HREA for exposure and health risk estimates (II.C.1); the approach taken to estimate exposures, key exposure results, and important uncertainties (II.C.2); and the approaches taken to estimate O_3 health risks, key risk results, and important uncertainties (II.C.3).

1. Air Quality Adjustment

As discussed above (section I.E), O_3 is formed near the Earth's surface due to chemical interactions involving solar radiation and precursor pollutants including VOCs, NO_X, CH_4 and CO. The response of O_3 to changes in precursor concentrations is nonlinear. In particular, NO_X causes both the formation and destruction of O_3. The net impact of NO_X emissions on O_3 concentrations depends on the local quantities of NO_X, VOC, and sunlight, which interact in a set of complex chemical reactions. In some areas, such as urban centers where NO_X emissions typically are high, NO_X leads to the net destruction of O_3, decreasing O_3 concentrations in the immediate vicinity. This phenomenon is particularly pronounced under conditions that lead to low ambient O_3 concentrations (*i.e.* during cool, cloudy weather and at night when photochemical activity is limited or nonexistent). However, while NO_X can initially destroy O_3 near emission sources, these same NO_X emissions eventually react to form O_3 downwind of those sources. Photochemical model simulations suggest that reductions in NO_X emissions will slightly increase O_3 concentrations near NO_X sources on days with lower O_3 concentrations, while at the same time decreasing the highest O_3 concentrations in outlying areas. The atmospheric chemistry that influences ambient O_3 concentrations is discussed in more detail in the ISA (U.S. EPA, 2013a, Chapter 3) and the PA (U.S. EPA, 2014c, Chapter 2) (see also Frey, 2014a, pp. 10 and 11).

The HREA uses a photochemical model to estimate sensitivities of O_3 to changes in precursor emissions in order to estimate ambient O_3 concentrations that would just meet the current and alternative standards (U.S. EPA, 2014a, Chapter 4).[61] For the 15 urban study areas evaluated in the HREA,[62] this model-based adjustment approach estimates hourly O_3 concentrations at each monitor location when modeled U.S. anthropogenic precursor emissions (*i.e.,* NO_X, VOC)[63] are reduced. The HREA estimates air quality that just meets the current and alternative standards for the 2006–2008 and 2008–2010 periods.[64]

As discussed in Chapter 4 of the HREA (U.S. EPA, 2014a), this approach to adjusting air quality models the physical and chemical atmospheric processes that influence ambient O_3 concentrations. Compared to the quadratic rollback approach used in previous reviews, it provides more realistic estimates of the spatial and temporal responses of O_3 to reductions in precursor emissions. Because ambient NO_X can contribute both to the formation and destruction of O_3 (U.S. EPA, 2014a, Chapter 4), as discussed above, the response of ambient O_3 concentrations to reductions in NO_X emissions is more variable than indicated by the quadratic rollback approach. This improved approach to adjusting O_3 air quality is consistent with recommendations from the National Research Council of the National Academies (NRC, 2008). In addition, CASAC strongly supported the improved approach, stating that ''the quadratic rollback approach has been replaced by a scientifically more valid Higher-order Decoupled Direct Method (HDDM)'' and that ''[t]he replacement of the quadratic rollback procedure by the HDDM procedure is important and supported by the CASAC'' (Frey, 2014a, pp.1 and 3).

Consistent with the O_3 chemistry summarized above, in locations and time periods when NO_X is predominantly contributing to O_3 formation (*e.g.,* downwind of important NO_X sources, where the highest O_3 concentrations often occur), model-based adjustment to the current and alternative standards decreases

[61] The HREA uses the Community Multi-scale Air Quality (CMAQ) photochemical model instrumented with the higher order direct decoupled method (HDDM) to estimate O_3 concentrations that would occur with the achievement of the current and alternative O_3 standards (U.S. EPA, 2014a, Chapter 4).

[62] The urban study areas assessed are Atlanta, Baltimore, Boston, Chicago, Cleveland, Dallas, Denver, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, St. Louis, and Washington, DC.

[63] Exposure and risk analyses for most urban study areas focus on reducing U.S. anthropogenic NO_X emissions alone. The exceptions are Chicago and Denver. Exposure and risk analyses for Chicago and Denver are based on reductions in emissions of both NO_X and VOC (U.S. EPA, 2014a, section 4.3.3.1; Appendix 4D).

[64] These simulations are illustrative and do not reflect any consideration of specific control programs designed to achieve the reductions in emissions required to meet the specified standards. Further, these simulations do not represent predictions of when, whether, or how areas might meet the specified standards.

estimated ambient O_3 concentrations compared to recent monitored concentrations (U.S. EPA, 2014a, section 4.3.3.2). In contrast, in locations and time periods when NO_X is predominantly contributing to O_3 titration (*e.g.,* in urban centers with high concentrations of NO_X emissions, where ambient O_3 concentrations are often suppressed and thus relatively low [65]), model-based adjustment increases ambient O_3 concentrations compared to recent monitored concentrations (U.S. EPA, 2014a, section 4.3.3.2; Frey, 2014a, p. 10).

Within urban study areas, the overall impacts of model-based air quality adjustment are to reduce the O_3 concentrations at the upper ends of ambient distributions and to increase the O_3 concentrations at the lower ends of those distributions (U.S. EPA, 2014a, section 4.3.3.2, Figures 4–9 and 4–10).[66] Seasonal means of daily O_3 concentrations generally exhibit only modest changes upon model adjustment, reflecting the seasonal balance between daily decreases in relatively higher concentrations and increases in relatively lower concentrations (U.S. EPA, 2014a, Figures 4–9 and 4–10). The resulting compression in the seasonal distributions of ambient O_3 concentrations is evident in all of the urban study areas evaluated, though the degree of compression varies considerably across areas (U.S. EPA, 2014a, Figures 4–9 and 4–10).

This compression in the distributions of ambient O_3 concentrations has important implications for exposure and risk estimates in urban study areas. Estimates influenced largely by the upper ends of the distribution of ambient concentrations (*i.e.,* exposures of concern and lung function risk estimates, as discussed in sections 3.2.2 and 3.2.3.1 of the PA (U.S. EPA, 2014c)) decrease with adjustment of air quality to the current and alternative standards. In contrast, seasonal risk estimates influenced by the full distribution of ambient O_3 concentrations (*i.e.,* epidemiology-based risk estimates, as discussed in section 3.2.3.2 of the PA) either decrease or increase in response to air quality adjustment, depending on the balance between the daily decreases in high O_3 concentrations and increases in low O_3 concentrations.[67]

In their review of the second draft HREA, CASAC considered this issue, in particular noting that ''reductions in nitrogen oxides emissions can lead to less scavenging of ozone and free radicals, resulting in locally higher levels of ozone'' (Frey, 2014a, p. 10). CASAC recommended that ''the EPA should identify and discuss whether and to what extent health risks in the urban core may be affected by NO_X reductions or other possible strategies'' and, in particular, concluded that it would ''be of interest to learn if there would be any children or outdoor workers in the more urban areas who would experience significantly higher exposures to ozone as a result of possible changes in the ozone NAAQS'' (Frey, 2014a, p. 10). Consistent with this advice, the exposure and risk implications of the spatial and temporal patterns of ambient O_3 following air quality adjustment in urban study areas are discussed in the final HREA (U.S. EPA, 2014a, Chapter 9) and the final PA (U.S. EPA, 2014c, sections 3.2.2, 3.2.3), and are summarized below within the context of the PA's consideration of exposure estimates (II.D.2.a) and risk estimates (II.D.2.b and II.D.2.c).

2. Exposure Assessment

This section discusses the HREA assessment of human exposures to O_3. Section II.C.2.a provides an overview of the approach used in the HREA to assessing exposures and the approach in the PA to considering exposure estimates, and summarizes key results. Section II.C.2.b summarizes the important uncertainties in exposure estimates.

a. Overview and Summary of Key Results

The exposure assessment presented in the HREA (U.S. EPA, 2014a, Chapter 5) provides estimates of the number and percent of people exposed to various concentrations of ambient O_3, while at specified exertion levels. The HREA estimates exposures in the 15 urban study areas for four study groups, all school-age children (ages 5 to 18), asthmatic school-age children, asthmatic adults (ages 19 to 95), and all older adults (ages 65 to 95), reflecting the evidence indicating that these populations are at increased risk for O_3-attributable effects (U.S. EPA, 2013a, Chapter 8). An important purpose of these exposure estimates is to provide perspective on the extent to which air quality adjusted to just meet the current O_3 NAAQS could be associated with exposures to O_3 concentrations reported to result in respiratory effects.[68] Estimates of such ''exposures of concern'' provide perspective on the potential public health impacts of O_3-related effects, including effects that cannot currently be evaluated in a quantitative risk assessment.[69]

In the absence of large scale exposure studies that encompass the general population, as well as at-risk populations, modeling is the preferred approach to estimating exposures to O_3 (U.S. EPA, 2014a, Chapter 5). The use of exposure modeling also facilitates the estimation of exposures resulting from ambient O_3 concentrations differing from those present during exposure studies. In the HREA, population exposures to ambient O_3 concentrations are estimated using the current version of the Air Pollutants Exposure (APEX) model. The APEX model simulates the movement of individuals through time and space and estimates their exposures to a given pollutant in indoor, outdoor, and in-vehicle microenvironments (U.S. EPA, 2014a, section 5.1.3). APEX takes into account important factors that contribute to total human exposure to ambient O_3, including the temporal and spatial distributions of people and O_3 concentrations throughout an urban area, the variation of O_3 concentrations within various microenvironments, and the effects of exertion on breathing rate in exposed individuals (U.S. EPA, 2014a, section 5.1.3). To the extent spatial and/or temporal patterns of ambient O_3 concentrations are altered upon model adjustment, as discussed above, exposure estimates reflect population exposures to those altered patterns.

The HREA estimates 8-hour exposures at or above benchmark concentrations of

[65] Titration is also prominent during time periods when photochemistry is limited, and ambient O_3 concentrations are relatively low, such as at night and on cool, cloudy days (U.S. EPA, 2014a, Chapter 4).

[66] It is important to note that sensitivity analyses in the HREA indicate that the increases in low O_3 concentrations are smaller when NO_X and VOC emissions are reduced than when only NO_X emissions are reduced (U.S. EPA, 2014a, Appendix 4–D, section 4.7).

[67] In addition, because epidemiology-based risk estimates use ''area-wide'' average O_3 concentrations, calculated by averaging concentrations across multiple monitors in urban study areas (U.S. EPA, 2014c, section 3.2.3.2), risk estimates on a given day depend on the daily balance between increasing and decreasing O_3 concentrations at the individual monitors that are averaged together to calculate the ''area-wide'' concentration.

[68] In addition, the range of modeled personal exposures to ambient O_3 provide an essential input to the portion of the health risk assessment based on exposure-response functions (for lung function decrements) from controlled human exposure studies. The health risk assessment based on exposure-response information is discussed below (II.C.3).

[69] In this review, the term ''exposure of concern'' is defined as a personal exposure, while at moderate or greater exertion, to 8-hour average ambient O_3 concentrations at and above specific benchmarks. As discussed below, benchmarks represent exposure concentrations at which O_3-induced health effects are known to occur, or can reasonably be anticipated to occur, in some individuals.

60, 70, and 80 ppb for individuals engaged in moderate or greater exertion (*i.e.,* to approximate conditions in the controlled human exposure studies on which benchmarks are based). Benchmarks reflect exposure concentrations at which O_3-induced respiratory effects are known to occur in some healthy adults engaged in moderate, intermittent exertion, based on evidence from controlled human exposure studies (U.S. EPA, 2013a, section 6.2; U.S. EPA, 2014c, section 3.1.2.1). The amount of weight to place on the estimates of exposures at or above specific benchmark concentrations depends in part on the weight of the scientific evidence concerning health effects associated with O_3 exposures at those benchmark concentrations. It also depends on judgments about the importance, from a public health perspective, of the health effects that are known or can reasonably be inferred to occur as a result of exposures at benchmark concentrations (U.S. EPA, 2014c, sections 3.1.3, 3.1.5).

As discussed in more detail above (II.B.2), the health evidence that supports evaluating exposures of concern at or above benchmark concentrations of 60, 70, and 80 ppb comes from a large body of controlled human exposure studies reporting a variety of respiratory effects in healthy adults. The lowest O_3 exposure concentration for which controlled human exposure studies have reported respiratory effects in healthy adults is 60 ppb (based on changes in group mean responses), with more evidence supporting this benchmark concentration in the current review than in the last review. In healthy adults, 6.6 hour exposures to 60 ppb O_3 have been reported to decrease lung function and to increase airway inflammation. Exposures of healthy adults to 72 ppb O_3 for 6.6 hours have been reported to result in larger average lung function decrements, compared to 60 ppb, as well as in increased respiratory symptoms. Exposures of healthy adults to 80 ppb O_3 for 6.6 hours have been reported to result in larger average lung function decrements than following exposures to 60 or 72 ppb and, depending on the study, to increase airway inflammation, increase respiratory symptoms, increase airways responsiveness, and decrease lung host defense (based on changes in group means) (U.S. EPA, 2014c, section 3.1.2.1). In commenting on the evidence for benchmark concentrations, CASAC stated the following (Frey, 2014c, p. 6):

> The 80 ppb-8hr benchmark level represents an exposure level for which there is substantial clinical evidence demonstrating a range of ozone-related effects including lung inflammation and airway responsiveness in healthy individuals. The 70 ppb-8hr benchmark level reflects the fact that in healthy subjects, decreases in lung function and respiratory symptoms occur at concentrations as low as 72 ppb and that these effects almost certainly occur in some people, including asthmatics and others with low lung function who are less tolerant of such effects, at levels of 70 ppb and below. The 60 ppb-8hr benchmark level represents the lowest exposure level at which ozone-related effects have been observed in clinical studies of healthy individuals. Based on its scientific judgment, the CASAC finds that the 60 ppb-8hr exposure benchmark is relevant for consideration with respect to adverse effects on asthmatics.

In considering estimates of O_3 exposures of concern at or above benchmarks of 60, 70, and 80 ppb, the PA focuses on modeled exposures for school-age children (ages 5–18), including asthmatic school-age children, which are key at-risk populations identified in the ISA (U.S. EPA, 2014c, section 3.1.5). The percentages of children estimated to experience exposures of concern are considerably larger than the percentages estimated for adult populations (*i.e.,* approximately 3-fold larger across urban study areas) (U.S. EPA, 2014a, section 5.3.2 and Figures 5–5 to 5–8). The larger exposure estimates for children are due primarily to the larger percentage of children estimated to spend an extended period of time being physically active outdoors when O_3 concentrations are elevated (U.S. EPA, 2014a, sections 5.3.2 and 5.4.1).

Although exposure estimates differ between children and adults, the patterns of results across the urban study areas and years are similar among all of the populations evaluated (U.S. EPA, 2014a, Figures 5–5 to 5–8). Therefore, while the PA highlights estimates in children, including asthmatic school-age children, it also notes that the patterns of exposures estimated for children represent the patterns estimated for adult asthmatics and older adults.

Table 1 below summarizes key results from the exposure assessment. Table 1 presents estimates of the percentages and numbers of all school-aged children estimated to experience exposures of concern when air quality was adjusted to just meet the current and alternative 8-hour O_3 standards. The percentage of all school-age children in the 15 urban study areas estimated to experience exposures of concern declines when comparing just meeting the current standard to just meeting alternative 8-hour O_3 standards. Substantial variability is evident across years and urban study areas, as indicated by the ranges of averaged estimates and estimates for worst-case years and study areas. As discussed below, the interindividual variability in responsiveness following exposures of concern means that only a subset of individuals who are exposed at and above a given benchmark concentration would actually be expected to experience respiratory effects.

TABLE 1—SUMMARY OF ESTIMATED EXPOSURES OF CONCERN IN ALL SCHOOL-AGE CHILDREN FOR THE CURRENT AND ALTERNATIVE O_3 STANDARDS IN URBAN STUDY AREAS

Benchmark concentration	Standard level (ppb)	Average % children exposed [70]	Average number of children exposed [average number of asthmatic children] [71]	% Children—worst year and worst area
One or more exposures of concern per season				
≥80 ppb	75	0–0.3	27,000 [3,000]	1.1
	70	0–0.1	3,700 [300]	0.2
	65	0	300 [0]	0
	60	0	100 [72] [0]	0
≥70 ppb	75	0.6–3.3	362,000 [40,000]	8.1
	70	0.1–1.2	94,000 [10,000]	3.2
	65	0–0.2	14,000 [2,000]	0.5
	60	0	1,400 [200]	0.1
≥60 ppb	75	9.5–17	2,316,000 [246,000]	25.8
	70	3.3–10.2	1,176,000 [126,000]	18.9
	65	0–4.2	392,000 [42,000]	9.5

TABLE 1—SUMMARY OF ESTIMATED EXPOSURES OF CONCERN IN ALL SCHOOL-AGE CHILDREN FOR THE CURRENT AND ALTERNATIVE O_3 STANDARDS IN URBAN STUDY AREAS—Continued

Benchmark concentration	Standard level (ppb)	Average % children exposed [70]	Average number of children exposed [average number of asthmatic children] [71]	% Children—worst year and worst area
	60	0–1.2	70,000 [8,000]	2.2
Two or more exposures of concern per season				
≥80 ppb	75	0	600 [100]	0.1
	70	0	0 [0]	0
	65	0	0 [0]	0
	60	0	0 [0]	0
≥70 ppb	75	0.1–0.6	46,000 [5,000]	2.2
	70	0–0.1	5,400 [600]	0.4
	65	0	300 [100]	0
	60	0	0 [0]	0
≥60 ppb	75	3.1–7.6	865,000 [93,000]	14.4
	70	0.5–3.5	320,000 [35,000]	9.2
	65	0–0.8	67,000 [7,500]	2.8
	60	0–0.2	5,100 [700]	0.3

b. Key Uncertainties

In considering exposure estimates within the context of the current and alternative O_3 standards, the PA also notes important uncertainties in these estimates. For example, due to variability in responsiveness, only a subset of individuals who experience exposures at or above a benchmark concentration can be expected to experience health effects.[73] Given the lack of sufficient exposure-response information for most of the health effects that informed benchmark concentrations, estimates of the number of people likely to experience exposures at or above benchmark concentrations generally cannot be translated into quantitative estimates of the number of people likely to experience specific health effects.[74] The PA views health-relevant exposures as a continuum with greater confidence and less uncertainty about the existence of adverse health effects at higher O_3 exposure concentrations, and less confidence and greater uncertainty as one considers lower exposure concentrations. This view draws from the overall body of available health evidence, which indicates that as exposure concentrations increase, the incidence, magnitude, and severity of effects increases.

Though the PA indicates less confidence in the likelihood of adverse health effects as O_3 exposure concentrations decrease, it also notes that the controlled human exposure studies that provided the basis for health benchmark concentrations have not evaluated at-risk populations. Compared to the healthy individuals included in controlled human exposure studies, members of at-risk populations (*e.g.,* asthmatics, children) could be more likely to experience adverse effects, could experience larger and/or more serious effects, and/or could experience effects following exposures to lower O_3 concentrations. The CASAC expressed similar views in their advice to the Administrator (Frey, 2014a, pp. 7 and 14). In considering estimated exposures of concern (U.S. EPA, 2014c, section 3.4), the PA notes that concerns about the potential for adverse health effects, including effects in at-risk populations must be balanced against the increasing uncertainty regarding the likelihood of such effects following exposures to lower O_3 concentrations.

Uncertainties associated with the APEX exposure modeling also have the potential to be important (U.S. EPA, 2014a, section 5.5.2, Table 5–6). For example, the HREA concludes that exposures of concern could be underestimated for some individuals who are frequently and routinely active outdoors during the warm season (U.S. EPA, 2014a, section 5.5.2). This could include outdoor workers and children who are frequently active outdoors. The HREA specifically notes that long-term diary profiles (*i.e.,* monthly, annual) do not exist for such populations, limiting the extent to which APEX outputs reflect people who follow similar daily routines resulting in high exposures, over extended periods of time.

In order to evaluate one dimension of the potential implications of this uncertainty for exposure estimates, the HREA reports the results of limited exposure model sensitivity analyses using subsets of activity diaries specifically selected to reflect groups spending a larger proportion of time being active outdoors during the O_3 season. When diaries were selected to mimic activity patterns performed by outdoor workers, the percent of modeled individuals estimated to experience exposures of concern was higher than the other adult populations evaluated. The percentages of outdoor workers estimated to experience exposures of concern were generally similar to the percentages estimated for children (*i.e.,* using the full database of diary profiles) in the worst-case urban study area and year (*i.e.,* urban study area and year with the largest percent of children estimated to experience exposures of concern) (U.S. EPA, 2014a, section 5.4.3.2, Figure 5–14). In

[70] Estimates for each urban case study area were averaged for the years evaluated in the HREA (2006 to 2010). Ranges reflect the ranges across urban study areas. Estimates smaller than 0.05% were rounded downward to zero (from U.S. EPA, 2014a, Tables 5–11 and 5–12).

[71] Numbers of children exposed in each urban case study area were averaged over the years 2006 to 2010. These averages were then summed across urban study areas. Numbers were rounded to nearest thousand unless otherwise indicated. Estimates smaller than 50 were rounded downward to zero (from U.S. EPA, 2014a, Appendix 5F Table 5F–5). See below for discussion of uncertainties in exposure estimates.

[72] As discussed in section 4.3.3 of the HREA, the model-based air quality adjustment approach used to estimate risks associated with the current and alternative standards was unable to estimate the distribution of ambient O_3 concentrations in New York City upon just meeting an alternative standard with a level of 60 ppb. Therefore, for the 60 ppb standard level the numbers of children and asthmatic children reflect all of the urban study areas except New York.

[73] As noted below (II.C.3.a.ii), in the case of asthmatics, responsiveness to O_3 could depend on factors that have not been well-evaluated, such as asthma severity, the effectiveness of asthma control, or the prevalence of medication use.

[74] The exception to this is lung function decrements, as discussed below (and in U.S. EPA, 2014c, section 3.2.3.1).

addition, when diaries were restricted to children who did not report any time spent inside a school or performing paid work (*i.e.,* to mimic children spending large portions of their time outdoors during the summer), the number experiencing exposures of concern increased by approximately 30% (U.S. EPA, 2014a, section 5.4.3.1). Though these sensitivity analyses are limited to single urban study areas, and though there is uncertainty associated with diary selection approaches to mimic highly exposed populations, they suggest the possibility that some at-risk groups could experience more frequent exposures of concern than indicated by estimates made using the full database of activity diary profiles.

In further considering activity diaries, the HREA also notes that growing evidence indicates that people can change their behavior in response to high O_3 concentrations, reducing the time spent being active outdoors (U.S. EPA, 2014a, section 5.4.3.3). Commonly termed ''averting behaviors,'' these altered activity patterns could reduce personal exposure concentrations. Therefore, the HREA also performed limited sensitivity analyses to evaluate the potential implications of averting behavior for estimated exposures of concern. These analyses suggest that averting behavior could reduce the percentages of children estimated to experience exposures of concern at or above the 60 or 70 ppb benchmark concentrations by approximately 10 to 30%, with larger reductions possible for the 80 ppb benchmark (U.S. EPA, 2014a, Figure 5–15). As discussed above for other sensitivity analyses, these analyses are limited to a single urban case study area and are subject to uncertainties associated with assumptions about the prevalence and duration of averting behaviors. However, the results suggest that exposures of concern could be overestimated, particularly in children (Neidell, 2009; U.S. EPA, 2013, Figures 4–7 and 4–8), if the possibility for averting behavior is not incorporated into estimates.

3. Quantitative Health Risk Assessments

For some health endpoints, there is sufficient scientific evidence and information available to support the development of quantitative estimates of O_3-related health risks. In the last review of the O_3 NAAQS, the quantitative health risk assessment estimated O_3-related lung function decrements, respiratory symptoms, respiratory-related hospital admissions, and nonaccidental and cardiorespiratory-related mortality (U.S. EPA, 2007). In those analyses, both controlled human exposure and epidemiologic studies were used for the quantitative assessment of O_3-related human health risks.

In the current review, for short-term O_3 concentrations, the HREA estimates lung function decrements; respiratory symptoms in asthmatics; hospital admissions and emergency department visits for respiratory causes; and all-cause mortality (U.S. EPA, 2014a). For long-term O_3 concentrations, the HREA estimates respiratory mortality (U.S. EPA, 2014a).[75] Estimates of O_3-induced lung function decrements are based on exposure modeling, combined with exposure-response relationships from controlled human exposure studies (U.S. EPA, 2014a, Chapter 6). Estimates of O_3-associated respiratory symptoms, hospital admissions and emergency department visits, and mortality are based on concentration-response relationships from epidemiologic studies (U.S. EPA, 2014a, Chapter 7). As with the exposure assessment discussed above, O_3-associated health risks are estimated for recent air quality and for ambient concentrations adjusted to just meet the current and alternative O_3 standards, based on 2006–2010 air quality and adjusted precursor emissions. The following sections discuss the lung function risk assessment (II.C.3.a) and the epidemiology-based morbidity and mortality risk assessments (II.C.3.b) from the HREA, including important sources of uncertainty in these estimates.

a. Lung Function Risk Assessment

Section II.C.3.a.i provides an overview of the approach used in the HREA to assessing lung function risks, an overview of the approach in the PA to considering lung function risk estimates, and a summary of key results. Section II.C.3.a.ii presents a summary of key uncertainties in lung function risk estimates.

i. Overview and Summary of Key Results

In the current review, the HREA estimates risks of lung function decrements in school-aged children (ages 5 to 18), asthmatic school-aged children, and the general adult population for the 15 urban study areas. The results presented in the HREA are based on an updated dose-threshold model that estimates FEV_1 responses for individuals following short-term exposures to O_3 (McDonnell et al., 2012), reflecting methodological improvements since the last review (II.B.2.a.i, above; U.S. EPA, 2014a, section 6.2.4). The impact of the dose threshold is that O_3-induced FEV_1 decrements result primarily from exposures on days with average ambient O_3 concentrations above about 40 ppb (U.S. EPA, 2014a, section 6.3.1, Figure 6–9).[76]

The HREA estimates risks of moderate to large lung function decrements, defined as FEV_1 decrements ≥10%, 15%, or 20%. In evaluating these lung function risk estimates within the context of considering the current and alternative O_3 standards, the PA focuses on the percent of children estimated to experience one or more and two or more decrements ≥10, 15, and 20%, noting that the percentage of asthmatic children estimated to experience such decrements is virtually indistinguishable from the percentage estimated for all children.[77] Compared to children, a smaller percentage of adults were estimated to experience O_3-induced FEV_1 decrements (U.S. EPA, 2014a, section 6.3.1, Table 6–4). As for exposures of concern (see above), the patterns of results across urban study areas and over the years evaluated are similar in children and adults. Therefore, while the PA highlights estimates in children, it notes that these results are also representative of the patterns estimated for adult populations.

Table 2 below summarizes key results from the lung function risk assessment. Table 2 presents estimates of the percentages of school-aged children estimated to experience O_3-induced FEV_1 decrements ≥10, 15, or 20% when air quality was adjusted to just meet the current and alternative 8-hour O_3 standards. Table 2 also presents the numbers of children, including children with asthma, estimated to experience such decrements. As shown in these tables, the percentage of school-age children in the 15 urban study areas estimated to experience O_3-induced FEV_1 decrements declines when comparing just meeting the current standard to just meeting alternative

[75] Estimates of O_3-associated respiratory mortality are based on the study by Jerrett et al. (2009). This study used seasonal averages of 1-hour daily maximum O_3 concentrations to estimate long-term concentrations.

[76] Analysis of this issue in the HREA is based on risk estimates in Los Angeles for 2006 unadjusted air quality. The HREA shows that more than 90% of daily instances of FEV_1 decrements ≥10% occur when 8-hr average ambient concentrations are above 40 ppb for this modeled scenario. The HREA notes that the distribution of responses will be different for different study areas, years, and air quality scenarios (U.S. EPA, 2014c, Chapter 6).

[77] Though see below for discussion of uncertainty in lung function responses of children and asthmatics.

8-hour O_3 standards. Substantial variability is evident across years and urban study areas, as indicated by the ranges of averaged estimates and estimates for worst-case years and locations.

TABLE 2—SUMMARY OF ESTIMATED O_3-INDUCED LUNG FUNCTION DECREMENTS FOR THE CURRENT AND POTENTIAL ALTERNATIVE O_3 STANDARDS IN URBAN CASE STUDY AREAS

Lung function decrement	Alternative standard level	Average % children [78]	Number of children (5 to 18 years) [number of asthmatic children] [79]	% Children worst year and area
One or more decrements per season				
≥10%	75	14–19	3,007,000 [312,000]	22
	70	11–17	2,527,000 [261,000]	20
	65	3–15	1,896,000 [191,000]	18
	60	5–11	1,404,000 [139,000] [80]	13
≥15%	75	3–5	766,000 [80,000]	7
	70	2–4	562,000 [58,000]	5
	65	0–3	356,000 [36,000]	4
	60	1–2	225,000 [22,000]	3
≥20%	75	1–2	285,000 [30,000]	2.8
	70	1–2	189,000 [20,000]	2.1
	65	0–1	106,000 [11,000]	1.4
	60	0–1	57,000 [6,000]	0.9
Two or more decrements per season				
≥10%	75	7.5–12	1,730,000 [179,000]	14
	70	5.5–11	1,414,000 [145,000]	13
	65	1.3–8.8	1,023,000 [102,000]	11
	60	2.1–6.4	741,000 [73,000]	7.3
≥15%	75	1.7–2.9	391,000 [40,000]	3.8
	70	0.9–2.4	276,000 [28,000]	3.1
	65	0.1–1.8	168,000 [17,000]	2.3
	60	0.2–1.0	101,000 [10,000]	1.4
≥20%	75	0.5–1.1	128,000 [13,000]	1.5
	70	0.3–0.8	81,000 [8,000]	1.1
	65	0–0.5	43,000 [4,000]	0.8
	60	0–0.2	21,000 [2,000]	0.4

ii. Key Uncertainties

As for exposures of concern discussed above, the PA also considers important uncertainties in estimates of lung function risk. In addition to the uncertainties noted for exposure estimates, the HREA identifies several key uncertainties associated with estimates of O_3-induced lung function decrements. An uncertainty with particular potential to impact consideration of risk estimates stems from the lack of exposure-response information in children. In the near absence of controlled human exposure data for children, risk estimates are based on the assumption that children exhibit the same lung function response following O_3 exposures as healthy 18 year olds (*i.e.,* the youngest age for which controlled human exposure data is available) (U.S. EPA, 2014a, section 6.5.3). This assumption is justified in part by the findings of McDonnell et al. (1985), who reported that children (8–11 years old) experienced FEV_1 responses similar to those observed in adults (18–35 years old). In addition, as discussed in the ISA (U.S. EPA, 2013a, section 6.2.1), summer camp studies of school-aged children reported O_3-induced lung function decrements similar in magnitude to those observed in controlled human exposure studies using adults. In extending the risk model to children, the HREA fixes the age term in the model at its highest value, the value for age 18. This approach could result in either over- or underestimates of O_3-induced lung function decrements in children, depending on how children compare to the adults used in controlled human exposure studies (U.S. EPA, 2014a, section 6.5.3).

A related source of uncertainty is that the risk assessment estimates O_3-induced decrements in asthmatics using the exposure-response relationship developed from data collected from healthy individuals. Although the evidence has been mixed (U.S. EPA, 2013a, section 6.2.1.1), several studies have reported larger O_3-induced lung function decrements in asthmatics than in non-asthmatics (Kreit et al., 1989; Horstman et al., 1995; Jorres et al., 1996; Alexis et al., 2000). On this issue, CASAC noted that ''[a]sthmatic subjects appear to be at least as sensitive, if not more sensitive, than non-asthmatic subjects in manifesting ozone-induced pulmonary function decrements'' (Frey, 2014c, p. 4). To the extent asthmatics experience larger O_3-induced lung function decrements than the healthy adults used to develop exposure-response relationships, the HREA could underestimate the impacts of O_3 exposures on lung function in asthmatics, including asthmatic children. The implications of this uncertainty for risk estimates remain unknown at this time (U.S. EPA, 2014a,

[78] Estimates in each urban case study area were averaged for the years evaluated in the HREA (2006 to 2010). Ranges reflect the ranges across urban study areas.

[79] Numbers of children estimated to experience decrements in each study urban case study area were averaged over 2006 to 2010. These averages were then summed across urban study areas. Numbers are rounded to nearest thousand unless otherwise indicated.

[80] As discussed in section 4.3.3 of the HREA, the model-based air quality adjustment approach used to estimate risks associated with the current and alternative standards was unable to estimate the distribution of ambient O_3 concentrations in New York City upon just meeting an alternative standard with a level of 60 ppb. Therefore, for the 60 ppb standard level the numbers of children and asthmatic children reflect all of the urban study areas except New York.

section 6.5.4), and could depend on a variety of factors that have not been well-evaluated, including the severity of asthma and the prevalence of medication use. However, the available evidence shows responses to O_3 increase with severity of asthma (Horstman et al., 1995) and corticosteroid usage does not prevent O_3 effects on lung function decrements or respiratory symptoms in people with asthma (Vagaggini et al., 2001, 2007).

b. Mortality and Morbidity Risk Assessments

As discussed above (II.B.2), epidemiologic studies provide evidence for the most serious O_3-associated public health outcomes (*e.g.,* mortality, hospital admissions, emergency department visits). Section II.C.3.b.i below provides an overview of the approach used in the HREA to assessing mortality and morbidity risks based on information from epidemiologic studies, discusses the approach in the PA to considering epidemiology-based risk estimates, and presents a summary of key results. Section II.C.3.b.ii summarizes key uncertainties in epidemiology-base risk estimates.

i. Overview and Summary of Key Results

Risk estimates based on epidemiologic studies can provide perspective on the most serious O_3-associated public health outcomes (*e.g.,* mortality, hospital admissions, emergency department visits) in populations that often include at-risk groups. The HREA estimates O_3-associated risks in 12 urban study areas [81] using concentration-response relationships drawn from epidemiologic studies. These concentration-response relationships are based on ''area-wide'' average O_3 concentrations.[82] The HREA estimates risks for the years 2007 and 2009 in order to provide estimates of risk for a year with generally higher O_3 concentrations (2007) and a year with generally lower O_3 concentrations (2009) (U.S. EPA, 2014a, section 7.1.1).

As in the last review of the O_3 NAAQS (U.S. EPA, 2007, pp. 2–48 to 2–54), the PA recognizes that ambient O_3 concentrations, and therefore O_3-associated health risks, result from precursor emissions from various types of sources. Based on the air quality modeling discussed in chapter 2 of the PA (U.S. EPA, 2014c), approximately 30 to 60% of average daytime O_3 during the warm season (*i.e.,* daily maximum 8-hour concentrations averaged from April to October) is attributable to precursor emissions from U.S. anthropogenic sources (U.S. EPA, 2014c, section 2.4.4). The remainder is attributable to precursor emissions from international anthropogenic sources and natural sources. Because the HREA characterizes health risks from all O_3, regardless of source, risk estimates reflect emissions from U.S. anthropogenic, international anthropogenic, and natural sources.

Compared to the weight given to HREA estimates of exposures of concern and lung function risks, and the weight given to the evidence (U.S. EPA, 2014c, section 4.4.1), the PA places relatively less weight on epidemiologic-based risk estimates. In doing so, the PA notes that the overall conclusions from the HREA likewise reflect less confidence in estimates of epidemiologic-based risks than in estimates of exposures and lung function risks. The determination to attach less weight to the epidemiologic-based estimates reflects the uncertainties associated with mortality and morbidity risk estimates, including the heterogeneity in effect estimates between epidemiologic study areas, the potential for epidemiologic-based exposure measurement error, and uncertainty in the interpretation of the shape of concentration-response functions at lower O_3 concentrations (discussed below). The PA also notes the HREA conclusion that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study (even though that study is well-designed) and because of the uncertainty in that study about the existence and level of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6).

In considering the epidemiology-based risk estimates, the PA focuses on mortality risks associated with short-term O_3 concentrations. In doing so, in addition to noting uncertainty in estimates of respiratory mortality associated with long-term O_3, the PA notes that the patterns of estimated respiratory morbidity risks across urban study areas, over years, and for different standards are similar to the patterns of total mortality risk.

The PA considers estimates of total risk (*i.e.,* based on the full distributions of ambient O_3 concentrations) and estimates of risk associated with O_3 concentrations in the upper portions of ambient distributions. A focus on estimates of total risks would place greater weight on the possibility that concentration-response relationships are linear over the entire distribution of ambient O_3 concentrations, and thus on the potential for morbidity and mortality to be affected by changes in relatively low O_3 concentrations. A focus on risks associated with O_3 concentrations in the upper portions of the ambient distribution would place greater weight on the uncertainty associated with the shapes of concentration-response curves for O_3 concentrations in the lower portions of the distribution. Given that both types of risk estimates could reasonably inform a decision on standard level, depending on the weight placed on uncertainties in the occurrence and the estimation of O_3-attributable effects at relatively low O_3 concentrations, the PA considers both types of estimates. Key results for O_3-associated mortality risk are summarized in Table 3 below. Table 3 presents estimates of the number of O_3-associated deaths in urban study areas, for air quality adjusted to just meet the current and alternative standards.

[81] The 12 urban areas evaluated are Atlanta, Baltimore, Boston, Cleveland, Denver, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, and St. Louis.

[82] In the epidemiologic studies that provide the health basis for HREA risk assessments, concentration-response relationships are based on daytime O_3 concentrations, averaged across multiple monitors within study areas. These daily averages are used as surrogates for the spatial and temporal patterns of exposures in study populations. Consistent with this approach, the HREA epidemiologic-based risk estimates also utilize daytime O_3 concentrations, averaged across monitors, as surrogates for population exposures. In this notice, we refer to these averaged concentrations as ''area-wide'' O_3 concentrations. Area-wide concentrations are discussed in more detail in section 3.1.4 of the PA (U.S. EPA, 2014c).

TABLE 3—ESTIMATES OF O_3-ASSOCIATED DEATHS ATTRIBUTABLE TO THE FULL DISTRIBUTION OF 8-HOUR AREA-WIDE O_3 CONCENTRATIONS AND TO CONCENTRATIONS AT OR ABOVE 20, 40, OR 60 PPB O_3

[Deaths summed across urban case study areas] [83]

Number of O_3-associated deaths summed across urban case study areas				
Standard level	Total O_3	20+ ppb	40+ ppb	60+ ppb
2007				
75 ppb	7,500	7,500	5,400	500
70 ppb	7,200	7,200	4,900	240
65 ppb	6,500	6,500	2,800	90
60 ppb [84]	6,400	6,400	2,300	10
2009				
75 ppb	7,000	7,000	4,700	270
70 ppb	6,900	6,900	4,300	80
65 ppb	6,400	6,400	2,600	40
60 ppb	6,300	6,300	2,100	10

ii. Key Uncertainties

Compared to estimates of O_3 exposures of concern and estimates of O_3-induced lung function decrements (discussed above), the HREA conclusions reflect lower confidence in epidemiologic-based risk estimates (U.S. EPA, 2014a, section 9.6). In particular, the HREA highlights the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions at lower O_3 concentrations (U.S. EPA, 2014a, section 9.6). The HREA also concludes that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3, primarily because that analysis is based on only one study, though that study is well-designed, and because of the uncertainty in that study about the existence and identification of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6).[85] [86] This section further discusses some of the key uncertainties in epidemiologic-based risk estimates, as summarized in the PA (U.S. EPA, 2014c, section 3.2.3.2), with a focus on uncertainties that can have particularly important implications for the Administrator's consideration of epidemiology-based risk estimates.

The PA notes that reducing NO_X emissions generally reduces O_3-associated mortality and morbidity risk estimates in locations and time periods with relatively high ambient O_3 concentrations and increases risk estimates in locations and time periods with relatively low concentrations (II.C.1, above). When evaluating uncertainties in epidemiologic risk estimates, it is important to consider (1) The extent to which the O_3 response to reductions in NO_X emissions appropriately represents the trends observed in ambient O_3 following actual reductions in NO_X emissions; (2) the extent to which estimated changes in risks in urban study areas are representative of the changes that would be experienced broadly across the U.S. population; and (3) the extent to which the O_3 response to reductions in precursor emissions could differ with emissions reduction strategies that are different from those used in HREA to generate risk estimates.

To evaluate the first issue, the HREA conducted a national analysis evaluating trends in monitored ambient O_3 concentrations during a time period when the U.S. experienced large-scale reductions in NO_X emissions (*i.e.,* 2001 to 2010). Analyses of trends in monitored O_3 indicate that over such a time period, the upper end of the distribution of monitored O_3 concentrations (*i.e.,* indicated by the 95th percentile) generally decreased in urban and non-urban locations across the U.S. (U.S. EPA, 2014a, Figure 8–29). During this same time period, median O_3 concentrations decreased in suburban and rural locations, and in some urban locations. However, median concentrations increased in some large urban centers (U.S. EPA, 2014a, Figure 8–28). As discussed in the REA, and above (II.C.1), these increases in median concentrations likely reflect the increases in relatively low O_3 concentrations that can occur near important sources of NO_X upon reductions in NO_X emissions (U.S. EPA, 2014a, section 8.2.3.1). These patterns of monitored O_3 during a period when the U.S. experienced large reductions in NO_X emissions are qualitatively consistent with the modeled responses of O_3 to reductions in NO_X emissions.

To evaluate the second issue, the HREA conducted national air quality modeling analyses. These analyses estimated the proportion of the U.S. population living in locations where seasonal averages of daily O_3 concentrations are estimated to decrease in response to reductions in NO_X emissions, and the proportion living in locations where such seasonal averages are estimated to increase. Given the close relationship between changes in

[83] Table 3 is based on the information in Figures 7–2 and 7–3 in the HREA (U.S. EPA, 2014a). Estimates of the numbers of O_3-associated deaths are based on concentration-response relationships for total mortality associated with short-term O_3 from the study by Smith et al. (2009). Estimates of the numbers O_3-associated deaths are rounded to the nearest hundred, unless otherwise indicated.

[84] As discussed in section 4.3.3 of the HREA, the model-based air quality adjustment approach used to estimate risks associated with the current and alternative standards was unable to estimate the distribution of ambient O_3 concentrations in New York City upon just meeting an alternative standard with a level of 60 ppb. Therefore, the total number of deaths indicated for the 60 ppb standard level reflect the 60 ppb estimates for all urban study areas except New York City. For New York City, the estimated number of O_3-associated deaths for the 60 ppb standard level was assumed to be equal to the number for the 65 ppb level.

[85] The CASAC also concluded that ''[i]n light of the potential nonlinearity of the C–R function for long-term exposure reflecting a threshold of the mortality response, the estimated number of premature deaths avoidable for long-term exposure reductions for several levels need to be viewed with caution'' (Frey, 2014a, p. 3).

[86] There is also uncertainty about the extent to which mortality estimates based on the long-term metric used in the study by Jerrett et al. (2009) (*i.e.,* seasonal average of 1-hour daily maximum concentrations) reflects associations with long-term average O_3 versus repeated occurrences of elevated short-term concentrations.

seasonal averages of daily O_3 concentrations and changes in seasonal mortality and morbidity risk estimates, this analysis informs consideration of the extent to which the risk results in urban study areas represent the U.S. population as a whole. This representativeness analysis indicates that the majority of the U.S. population lives in locations where reducing NO_X emissions would be expected to result in decreases in warm season averages of daily maximum 8-hour ambient O_3 concentrations. Because the HREA urban study areas tend to underrepresent the populations living in such areas (*e.g.,* suburban, smaller urban, and rural areas), risk estimates for the urban study areas are likely to understate the average reductions in O_3-associated mortality and morbidity risks that would be experienced across the U.S. population as a whole upon reducing NO_X emissions (U.S. EPA, 2014a, section 8.2.3.2).

To evaluate the third issue, the HREA assessed the O_3 air quality response to reducing both NO_X and VOC emissions (*i.e.,* in addition to assessing reductions in NO_X emissions alone) for a subset of seven urban study areas. As discussed in the PA (U.S. EPA, 2014c, section 3.2.1), in most of the urban study areas the inclusion of VOC emissions reductions did not alter the NO_X emissions reductions required to meet the current or alternative standards.[87] However, the addition of VOC reductions generally resulted in larger decreases in mid-range O_3 concentrations (25th to 75th percentiles) (U.S. EPA, 2014a, Appendix 4D, section 4.7).[88] In addition, in all seven of the urban study areas evaluated, the increases in low O_3 concentrations were smaller for the NO_X/VOC scenarios than the NO_X alone scenarios (U.S. EPA, 2014a, Appendix 4D, section 4.7). This was most apparent for Denver, Houston, Los Angeles, New York, and Philadelphia. Given the impacts on total risk estimates of increases in low O_3 concentrations, these results suggest that in some locations optimized emissions reduction strategies could result in larger reductions in O_3-associated mortality and morbidity than indicated by HREA estimates.

Section 7.4 of the HREA also highlights some additional uncertainties associated with epidemiologic-based risk estimates (U.S. EPA, 2014a). This section of the HREA identifies and discusses sources of uncertainty and presents a qualitative evaluation of key parameters that can introduce uncertainty into risk estimates (U.S. EPA, 2014a, Table 7–4). For several of these parameters, the HREA also presents quantitative sensitivity analyses (U.S. EPA, 2014a, sections 7.4.2 and 7.5.3). Of the uncertainties discussed in Chapter 7 of the HREA, those related to the application of concentration-response functions from epidemiologic studies can have particularly important implications for consideration of epidemiology-based risk estimates, as discussed below.

An important uncertainty is the shape of concentration-response functions at low ambient O_3 concentrations (U.S. EPA, 2014a, Table 7–4).[89] Consistent with the ISA conclusion that there is no discernible population threshold in O_3-associated health effects, the HREA estimates epidemiology-based mortality and morbidity risks for entire distributions of ambient O_3 concentrations, based on the assumption that concentration-response relationships remain linear over those distributions. In addition, in recognition of the ISA conclusion that certainty in the shape of O_3 concentration-response functions decreases at low ambient concentrations, the HREA also estimates total mortality associated with various ambient O_3 concentrations. The PA considers both types of risk estimates, recognizing greater public health concern for adverse O_3-attributable effects at higher ambient O_3 concentrations (which drive higher exposure concentrations, section 3.2.2 of the PA (U.S. EPA, 2014c)), as compared to lower concentrations.

A related uncertainty is that associated with the public health importance of the increases in relatively low O_3 concentrations following air quality adjustment. This uncertainty relates to the assumption that the concentration response function for O_3 is linear, such that that total risk estimates are equally influenced by decreasing high concentrations and increasing low concentrations, when the increases and decreases are of equal magnitude. Even on days with increases in relatively low area-wide average concentrations, resulting in increases in estimated risks, some portions of the urban study areas could experience decreases in high O_3 concentrations. To the extent adverse O_3-attributable effects are more strongly supported for higher ambient concentrations (which are consistently reduced upon air quality adjustment), the impacts on risk estimates of increasing low O_3 concentrations reflect an important source of uncertainty.

The HREA also notes important uncertainties associated with using a concentration-response relationship developed for a particular population in a particular location to estimate health risks in different populations and locations (U.S. EPA, 2014a, Table 7–4). As discussed above, concentration-response relationships derived from epidemiologic studies reflect the spatial and temporal patterns of population exposures during the study. The HREA applies concentration-response relationships from epidemiologic studies to adjusted air quality in study areas that are different from, and often larger in spatial extent than, the areas used to generate the relationships. This approach ensures the inclusion of the actual nonattainment monitors that often determine the magnitude of emissions reductions for the air quality adjustments throughout the urban study areas. This approach also allows the HREA to estimate patterns of health risks more broadly across a larger area, including a broader range of air quality concentrations and a larger population. The HREA notes that it is not possible to quantify the impacts of this uncertainty on risk estimates in most urban case study locations, though the HREA notes that mortality effect estimates for different portions of the New York City core based statistical area (CBSA) vary by a factor of almost 10 (U.S. EPA, 2014a, section 7.5.3).

An additional, related uncertainty is that associated with applying concentration-response functions from epidemiologic studies to adjusted air quality. Concentration-response functions from the O_3 epidemiologic studies used in the HREA are based on associations between day to day variation in ''area-wide'' O_3 concentrations (*i.e.,* averaged across multiple monitors) and variation in health effects. Epidemiologic studies use these area-wide O_3 concentrations, which reflect the particular spatial and temporal patterns of ambient O_3 present in study locations, as surrogates for the pattern of O_3 exposures experienced by study populations. To the extent adjusting O_3 concentrations to just meet the current standard results in important alterations in the spatial and/

[87] The exceptions are Chicago and Denver, for which the HREA risk estimates are based on reductions in both NO_X and VOC (U.S. EPA, 2014a, section 4.3.3.1). Emissions of NO_X and VOC were reduced by equal percentages, a scenario not likely to reflect the optimal combination for reducing risks.

[88] This was the case for all of the urban study areas evaluated, with the exception of New York (U.S. EPA, 2014a, Appendix 4–D, section 4.7).

[89] A related uncertainty is the existence, or not, of a threshold. The HREA addresses this issue for long-term O_3 by evaluating risks in models that include potential thresholds (II.D.2.c).

or temporal patterns of ambient O_3, there is uncertainty in the appropriateness of applying concentration-response functions from epidemiologic studies (which necessarily reflect a different air quality distribution than the modelled distribution) to estimate health risks associated with adjusted O_3 air quality. In particular, this uncertainty could be important to the extent that (1) factors associated with space modify the effects of O_3 on health or (2) spatial mobility is a key driver of individual-level exposures. Although the impact of this uncertainty on risk estimates cannot be quantified (U.S. EPA, 2014a, Table 7–4), it has the potential to become more important as model adjustment results in larger changes in spatial and temporal patterns of ambient O_3 concentrations across urban study areas.

The use of a national concentration-response function to estimate respiratory mortality associated with long-term O_3 is a source of uncertainty. Risk estimates generated in sensitivity analyses using region-specific effect estimates differ substantially from the core estimates based on a single national-level effect estimate (U.S. EPA, 2014a; Table 7–14). Furthermore, the risk estimates generated using the regional effect estimates display considerable variability across urban study areas (U.S. EPA, 2014a; Table 7–14), reflecting the substantial variability in the underlying effect estimates (see Jerrett et al., 2009, Table 4). While the results of the HREA sensitivity analyses evaluating this uncertainty point to the potential for regional heterogeneity in the long-term risk estimates, the relatively large confidence intervals associated with regional effect estimates resulted in the HREA conclusion that staff does not have confidence in the regionally based risk estimates themselves.

Finally, the HREA does not quantify any reductions in risk that could be associated with reductions in the ambient concentrations of pollutants other than O_3, resulting from control of NO_X. For example, as discussed in chapter 2 of the PA (U.S. EPA, 2014c), NO_X emissions contribute to ambient NO_2, and NO_X and VOCs can contribute to secondary formation of $PM_{2.5}$ constituents, including ammonium sulfate (NH_4SO_4), ammonium nitrate (NH_4NO_3), and organic carbon (OC). Therefore, at some times and in some locations, control strategies that would reduce NO_X emissions (*i.e.,* to meet an O_3 standard) could reduce ambient concentrations of NO_2 and $PM_{2.5}$, resulting in health benefits beyond those directly associated with reducing ambient O_3 concentrations. In issuing its advice, CASAC likewise noted the potential reductions in criteria pollutants other than ozone as a result of NOx reductions, and the resulting potential public health benefits (Frey, 2014a, pp. 10 and 11).

D. Conclusions on the Adequacy of the Current Primary Standard

The initial issue to be addressed in the current review of the primary O_3 standard is whether, in view of the advances in scientific knowledge and additional information, the existing standard should be revised. In evaluating whether it is appropriate to retain or revise the current standard, the Administrator's considerations build upon those in the 2008 review, including consideration of the broader body of scientific evidence and exposure and health risk information now available, as summarized above (II.A to II.C).

In developing conclusions on the adequacy of the current primary O_3 standard, the Administrator takes into account both evidence-based and quantitative exposure- and risk-based considerations. Evidence-based considerations include the assessment of evidence from controlled human exposure, animal toxicological, and epidemiologic studies for a variety of health endpoints. The Administrator focuses on health endpoints for which the evidence is strong enough to support a ''causal'' or a ''likely to be causal'' relationship, based on the ISA's integrative synthesis of the entire body of evidence. The Administrator's consideration of quantitative exposure and risk information draws from the results of the exposure and risk assessments presented in the HREA.

The Administrator's consideration of the evidence and exposure/risk information is informed by the considerations and conclusions presented in the PA (U.S. EPA, 2014c). The purpose of the PA is to help ''bridge the gap'' between the scientific and technical information assessed in the ISA and HREA, and the policy decisions that are required of the Administrator (U.S. EPA, 2014c, Chapter 1). The PA's evidence-based and exposure-/risk-based considerations and conclusions are summarized below in sections II.D.1 to II.D.3. CASAC advice to the Administrator and public commenter views are summarized in section II.D.4. Section II.D.5 presents the Administrator's proposed conclusions concerning the adequacy of the public health protection provided by the current standard, and her proposed decision to revise that standard.

1. Summary of Evidence-Based Considerations in the PA

In considering the available scientific evidence, the PA evaluates the O_3 concentrations in health effects studies (U.S. EPA, 2014c, section 3.1.4). Specifically, the PA characterizes the extent to which effects have been reported for the O_3 exposure concentrations evaluated in controlled human exposure studies and over the distributions of ambient O_3 concentrations in locations where epidemiologic studies have been conducted. These considerations, as they relate to the adequacy of the current standard, are presented in detail in section 3.1.4 of the PA (U.S. EPA, 2014c) and are summarized briefly below for controlled human exposure and epidemiologic panel studies (II.D.1.a), epidemiologic studies of short-term O_3 exposures (II.D.1.b), and epidemiologic studies of long-term O_3 exposures (II.D.1.c). Section II.D.1.d summarizes the PA conclusions based on consideration of the scientific evidence.

a. Concentrations in Controlled Human Exposure and Panel Studies

The evidence from controlled human exposure studies and panel studies is assessed in section 6.2 of the ISA (U.S. EPA, 2013a) and is summarized in section 3.1.2 of the PA (U.S. EPA, 2014c). As discussed above (II.B), controlled human exposure studies have generally been conducted with young, healthy adults, and have evaluated exposure durations less than 8 hours. Panel studies have evaluated a wider range of study populations, including children, and have generally evaluated associations with O_3 concentrations averaged over several hours (U.S. EPA, 2013a, section 6.2.1.2).[90]

As summarized above (II.B), a large number of controlled human exposure studies have reported lung function decrements, respiratory symptoms, airway inflammation, AHR, and/or impaired lung host defense in young, healthy adults engaged in moderate, intermittent exertion, following 6.6-hour O_3 exposures. These studies have consistently reported such effects following exposures to O_3 concentrations of 80 ppb or greater. In addition to lung function decrements, available studies have also evaluated respiratory symptoms or airway

[90] The PA focuses on panel studies that used on-site monitoring, and that are highlighted in the ISA for the extent to which monitored ambient O_3 concentrations reflect exposure concentrations in their study populations (U.S. EPA, 2013a, section 6.2.1.2).

inflammation following exposures to O_3 concentrations below 75 ppb. Table 3–1 in the PA highlights the group mean results of individual controlled human exposure studies that have evaluated exposures of healthy adults to O_3 concentrations below 75 ppb (U.S. EPA, 2014c). The studies included in Table 3–1 of the PA indicate a combination of lung function decrements and respiratory symptoms following 6.6 hour exposures to O_3 concentrations as low as 72 ppb, and lung function decrements and airway inflammation following 6.6 hour exposures to O_3 concentrations as low as 60 ppb (based on group means).

The PA also notes consistent results in some panel studies of O_3-associated lung function decrements. In particular, the PA notes that epidemiologic panel studies in children and adults consistently indicate O_3-associated lung function decrements when on-site monitored concentrations were below 75 ppb, although the evidence becomes less consistent at lower O_3 concentrations (U.S. EPA, 2014c, section 3.1.4.1).[91]

Thus, controlled human exposure studies and panel studies have reported respiratory effects in adults and children following exposures to O_3 concentrations below 75 ppb (albeit over shorter averaging periods than the 8 hour averaging time of the current O_3 standard). The PA notes that such impairments in respiratory function have the potential to be adverse, based on ATS guidelines for adversity and based on advice from CASAC (Frey, 2014c, pp. 5 and 6) (U.S. EPA, 2014c, section 3.1.3). In addition, the PA notes that if they become serious enough, these respiratory effects could lead to the types of clearly adverse effects commonly reported in O_3 epidemiologic studies (*e.g.,* respiratory emergency department visits, hospital admissions). Therefore, the PA concludes that the respiratory effects experienced following exposures to O_3 concentrations lower than 75 ppb could be adverse in some individuals, particularly if experienced by members of at-risk populations (*e.g.,* people with asthma, children).[92]

[91] As indicated in the PA (U.S. EPA, 2014c, Table 3–2), key O_3 panel studies evaluated averaging periods ranging from 10 minutes to 12 hours.

[92] These effects were reported in healthy individuals. Consistent with CASAC advice (Samet, 2011; Frey, 2014a, p. 14; Frey, 2014c, p. 7), it is a reasonable inference that the effects would be greater in magnitude and potential severity for at-risk groups. See *National Environmental Development Ass'n Clean Air Project* v. *EPA*, 686 F. 3d 803, 811 (D.C. Cir. (2012) (making this point).

b. Concentrations in Epidemiologic Studies—Short-Term

The PA also considers distributions of ambient O_3 concentrations in locations where epidemiologic studies have evaluated O_3-associated hospital admissions, emergency department visits, and/or mortality (U.S. EPA, 2014c, section 3.1.4.2). When considering epidemiologic studies within the context of the current standard, the PA emphasizes those studies conducted in the U.S. and Canada. Such studies reflect air quality and exposure patterns that are likely more typical of the U.S. population than the air quality and exposure patterns reflected in studies conducted outside the U.S. and Canada (U.S. EPA, 2014c, section 1.3.1.2).[93] The PA also emphasizes studies reporting associations with effects judged in the ISA to be robust to confounding by other factors, including co-occurring air pollutants. In addition to these factors, the PA considers the statistical precision of study results, the extent to which studies report associations in at-risk populations, and the extent to which the biological plausibility of associations at various ambient O_3 concentrations is supported by controlled human exposure and/or animal toxicological studies. These considerations help inform the range of ambient O_3 concentrations over which the evidence indicates the most confidence in O_3-associated health effects, and the range of concentrations over which confidence in such associations is appreciably lower.

This section summarizes the PA conclusions regarding the extent to which health effect associations have been reported for ambient O_3 concentrations likely to have met the current O_3 standard. Section II.D.1.b.i summarizes PA analyses and conclusions based on analyses evaluating the extent to which epidemiologic studies have reported health effect associations in locations that would likely have met the current O_3 standard. Section II.D.1.b.ii summarizes PA conclusions based on analyses evaluating the O_3 air quality in locations where epidemiologic studies have characterized confidence intervals around cut point analyses or concentration-response functions. Section II.D.1.b.iii summarizes the important uncertainties in these analyses.

[93] Nonetheless, the PA recognizes the importance of all studies, including international studies, in the ISA's assessment of the weight of the evidence that informs causality determinations.

i. Associations in Locations Likely Meeting Current Standard

The PA considers the extent to which U.S. and Canadian epidemiologic studies have reported associations with mortality or morbidity in locations that would likely have met the current O_3 standard during the study period (U.S. EPA, 2014c, section 3.14.2). Addressing this issue can provide important insights into the extent to which O_3-health effect associations are present for distributions of ambient O_3 concentrations that would be allowed by the current standard. To the extent associations are reported in study areas that would have met the current standard, those associations indicate that the current standard could allow the types of clearly adverse O_3-associated effects reported in epidemiologic studies (*e.g.,* mortality, hospital admissions, emergency department visits).[94] In considering these analyses, the PA also notes that the lack of such associations in locations meeting the current standard indicates increased uncertainty in the extent to which O_3-associated health effects would persist upon reducing O_3 precursor emissions in order to meet that standard.

The PA identifies U.S. and Canadian studies of respiratory hospital admissions, respiratory emergency department visits, and mortality (total, respiratory, cardiovascular) from the ISA (U.S. EPA, 2013a, Tables 6–28, 6–42, and 6–53, and section 6.2.8; U.S. EPA, 2014c, Appendix 3D). Analysis of study area air quality indicates that the large majority of epidemiologic study areas evaluated would have violated the current standard during study periods (U.S. EPA, 2014c, Appendix 3D). However, the PA notes that a single-city study conducted in Seattle, a location that would have met the current standard over the entire study period, reported positive and statistically significant associations with respiratory emergency department visits in children and adults (Mar and Koenig, 2009). The PA also notes four Canadian multicity studies that reported positive and statistically significant associations with respiratory morbidity or mortality, and for which the majority of study cities would have met the current standard over the entire study periods (Cakmak et

[94] See *ATA III,* 283 F.3d at 370 (EPA justified in revising NAAQS when health effect associations are observed in epidemiologic studies at levels allowed by the NAAQS); *State of Mississippi* v. *EPA,* 744 F. 3d at 1345 (same).

al., 2006; Dales et al., 2006; Katsouyanni et al., 2009; Stieb et al., 2009).[95]

The PA concludes that the single-city study by Mar and Koenig (2009) indicates the presence of associations with mortality and morbidity for an ambient distribution of O_3 that would have met the current standard (U.S. EPA, 2014c, section 3.1.4.2). The PA notes that interpretation of the air quality concentrations in the multicity study locations evaluated in this review is complicated by uncertainties in the extent to which multicity effect estimates can be attributed to ambient O_3 in the majority of locations, which would have met the current standard, versus O_3 in the smaller number of locations that would have violated the standard. While acknowledging this uncertainty in interpreting air quality in multicity studies, the PA notes that multicity effect estimates in the four studies cited above are largely influenced by locations meeting the current standard (*i.e.,* given that most study areas would have met this standard). Therefore, the PA concludes that Canadian multicity studies, in addition to the single-city study in Seattle, suggest confidence in the presence of associations with mortality and morbidity for ambient distributions of O_3 that would have met the current standard (U.S. EPA, 2014c, section 3.1.4.2).

ii. Air Quality Associated With Cut Point Analyses and Concentration-Response Functions

The PA also considers the extent to which additional epidemiologic studies of mortality or morbidity, specifically those conducted in locations that would have violated the current standard, can inform consideration of adequacy of the current standard (U.S. EPA, 2014c, section 3.1.4.2). In doing so, the PA notes that health effect associations reported in epidemiologic studies are influenced by the full distributions of ambient O_3 concentrations, including concentrations below the level of the current standard. The PA focuses on studies that have explicitly characterized O_3 health effect associations, including confidence in those associations, for various portions of distributions of ambient O_3 concentrations.

The U.S. multicity study by Bell et al. (2006) reported health effect associations for air quality subsets restricted to ambient O_3 concentrations below one or more predetermined cut points. In these analyses, effect estimates were based only on the subsets of days contributing to averaged O_3 concentrations below cut points ranging from 5 to 60 ppb (Bell et al., 2006, Figure 2).[96] The PA notes that such ''cut point'' analyses can provide information on the magnitude and statistical precision of effect estimates for defined distributions of ambient concentrations, which may in some cases include distributions that would meet the current standard (U.S. EPA, 2014c, section 3.1.4.2). The cut points below which confidence intervals become notably wider depend in large part on data density and, therefore, cut point analyses provide insight into the ambient concentrations below which the available air quality information becomes too sparse to support conclusions about the nature of concentration-response relationships with a high degree of confidence (U.S. EPA, 2014c, section 3.1.4.2).

The PA considers the extent to which the cut-point analyses reported by Bell et al. (2006) indicate health effect associations for distributions of ambient O_3 concentrations that would likely have met the current standard. The PA particularly focuses on the lowest cut-point for which the association between O_3 and mortality was reported to be statistically significant (*i.e.,* 30 ppb, based on visual inspection of Figure 2 in the published study). Based on the O_3 air quality concentrations that met the criteria for inclusion in the 30 ppb cut point analysis, 95% of study areas had 3-year averages of annual 4th highest daily maximum 8-hour O_3 concentration at or below 75 ppb over the entire study period (U.S. EPA, 2014c, section 3.1.4.2, Table 3–6). Though there are important uncertainties in this analysis, as discussed below, the PA concludes that these results suggest that the large majority of air quality distributions that provided the basis for the positive and statistically significant association with mortality at the 30 ppb cut point would likely have met the current O_3 standard.

The PA also analyzes air quality for studies that have reported confidence intervals around concentration-response functions over distributions of ambient O_3 concentrations (U.S. EPA, 2014c, section 3.1.4.2). Confidence intervals around concentration-response functions can provide insights into the range of ambient concentrations over which the study indicates the most confidence in the reported health effect associations (*i.e.,* where confidence intervals are narrowest), and into the range of ambient concentrations below which the study indicates that uncertainty in the nature of such associations becomes notably greater (*i.e.,* where confidence intervals become markedly wider). As with cut point analyses, the concentrations below which confidence intervals become markedly wider are intrinsically related to data density, and do not necessarily indicate the absence of an association.

The PA focuses on two U.S. single-city studies that have reported confidence intervals around concentration-response functions (Silverman and Ito, 2010; Strickland et al., 2010). Based on the published analyses, the PA identifies the ranges of ambient O_3 concentrations over which these studies indicate the highest degree of confidence in the reported linear concentration-response functions (U.S. EPA, 2014c, section 3.1.4.2). For the lower ends of these ranges, air quality analyses in the PA indicate that over 99% of days had maximum 8-hour O_3 concentrations (*i.e.,* from highest monitors in study locations) at or below 75 ppb. For comparison, the annual 4th highest daily maximum 8-hour O_3 concentration generally corresponds to the 98th or 99th percentile of the seasonal distribution, depending on the length of the O_3 season.

The PA concludes that these analyses of air quality data from the study locations evaluated by Silverman and Ito (2010) and Strickland et al. (2010) indicate a relatively high degree of confidence in reported statistical associations with respiratory health outcomes on days when virtually all monitored 8-hour O_3 concentrations were 75 ppb or below (U.S. EPA, 2014c, section 3.1.4.2). Though these analyses do not identify true design values, the presence of O_3-associated respiratory effects on such days provides insight into the types of health effects that could occur in locations with maximum ambient O_3 concentrations at or below the level of the current standard.

iii. Important Uncertainties

In considering the above evidence within the context of developing overall conclusions on the current and potential alternative standards, the PA also takes into account important uncertainties in these analyses of air quality in locations of epidemiologic study areas. These uncertainties are summarized in this

[95] In addition, a study by Vedal et al. (2003) was included in the 2006 AQCD (U.S. EPA, 2006a). This study reported positive and statistically significant associations with mortality in Vancouver during a time period when the study area would have met the current standard (U.S. EPA, 2007). This study was not assessed in the ISA in the current review (U.S. EPA, 2013a).

[96] In the published study, 2-day rolling averages of 24-hour average O_3 concentrations were calculated in each study location (based on averaging across monitors in study locations with multiple monitors).

section. The PA's consideration of the evidence, including the associated uncertainties, in reaching conclusions on the current and potential alternative standards is summarized in sections II.D.3 (current standard) and II.E.4.b (potential alternative standards) below.

The PA notes that while multicity studies generally have greater statistical power and geographic coverage than single-city studies, there is often greater uncertainty in conclusions about the extent to which multicity effect estimates reflect associations with air quality meeting the current standard (U.S. EPA, 2014c, section 1.3.1.2.1). This is particularly the case for the multicity studies evaluated in this review with some study locations meeting the current standard and others violating that standard. Specifically for the four Canadian multicity studies discussed above, the PA notes that interpretation of air quality information is complicated by uncertainties in the extent to which multicity effect estimates can be attributed to ambient O_3 in the majority of locations, which would have met the current standard, versus O_3 in the smaller number of locations that would have violated the standard.

The PA also notes important uncertainties in multicity studies that evaluate the potential for thresholds to exist, as was done in the study by Bell et al. (2006). Specifically, the ISA highlights the regional heterogeneity in O_3 health effect associations as a factor that could obscure the presence of thresholds, should they exist, in multicity studies (U.S. EPA, 2013a, sections 2.5.4.4 and 2.5.4.5). The ISA notes that community characteristics (*e.g.,* activity patterns, housing type, age distribution, prevalence of air conditioning) could be important contributors to reported regional heterogeneity (U.S. EPA, 2013a, section 2.5.4.5). Given this heterogeneity, the ISA concludes that ''a national or combined analysis may not be appropriate to identify whether a threshold exists in the O_3-mortality [concentration-response] relationship'' (U.S. EPA, 2013a, p. 2–33). This represents an important source of uncertainty when characterizing confidence in reported concentration-response relationships over distributions of ambient O_3 concentrations, based on multicity studies. The PA notes that this uncertainty becomes increasingly important when interpreting concentration-response relationships at lower ambient O_3 concentrations, particularly those concentrations corresponding to portions of distributions where data density decreases notably (U.S. EPA, 2014c, section 3.1.4.2).

Another important uncertainty, related specifically to the PA analysis of cut points by Bell et al. (2006), is that EPA staff was unable to obtain the air quality data used to generate the cut-point analyses in the published study (U.S. EPA, 2014c, section 3.1.4.2). Therefore, the analyses in the PA identified 2-day averages of 24-hour O_3 concentrations in study locations using the air quality data available in AQS, combined with the published description of study area definitions. An important uncertainty in this approach is the extent to which the PA appropriately recreated the cut-point analyses in the published study (U.S. EPA, 2014c, section 3.1.4.2).

An uncertainty that applies to epidemiologic studies in general is the extent to which reported health effects are caused by exposures to O_3 itself, as opposed to other factors such as co-occurring pollutants or pollutant mixtures. The PA notes that this uncertainty becomes an increasingly important consideration as health effect associations are evaluated at lower ambient O_3 concentrations. In particular, there is increasing uncertainty as to whether the observed associations remain plausibly related to exposures to ambient O_3, rather than to the broader mix of air pollutants present in the ambient air. In considering the potential importance of this uncertainty at the relatively low ambient O_3 concentrations that are the focus of the PA analyses, the PA notes that Silverman and Ito (2010) and Strickland (2010) reported O_3 health effect associations in co-pollutant models,[97] providing support for associations with O_3 itself (U.S. EPA, 2014c, section 3.1.4.2). The PA also concludes that air quality analyses indicate coherence with the results of experimental studies (*i.e.,* in which the study design dictates that exposures to O_3 itself are responsible for reported effects), and are consistent with the occurrence of O_3-attributable respiratory hospital admissions and emergency department visits, even when virtually all monitored concentrations were below the level of the current standard (U.S. EPA, 2014c, section 3.1.4.2, Tables 3–4, 3–5).

[97] In addition, Bell et al. (2006) reported that, based on a previous study (Bell et al., 2004), associations with mortality were robust to the inclusion of PM_{10} in the model.

c. Concentrations in Epidemiologic Studies—Long-Term

The PA also considers the extent to which epidemiologic studies employing longer-term ambient O_3 concentration metrics inform our understanding of the air quality conditions associated with O_3-attributable health effects, and specifically inform consideration of the extent to which such effects could occur under air quality conditions meeting the current standard (U.S. EPA, 2014c, section 3.1.4.3). Unlike for the studies of short-term O_3 discussed above, the available U.S. and Canadian epidemiologic studies evaluating long-term ambient O_3 concentration metrics have not been conducted in locations likely to have met the current 8-hour O_3 standard during the study period, and have not reported concentration-response functions that indicate confidence in health effect associations at O_3 concentrations meeting the current standard (U.S. EPA, 2014c, section 3.1.4.3). Therefore, although these studies contribute to understanding of health effects associated with long-term or repeated exposures to ambient O_3, consideration of study area air quality does not inform consideration of the extent to which those health effects may be occurring in locations that meet the current standard.

d. PA Conclusions Based on Consideration of the Evidence

As discussed above (II.D.1.a to II.D.1.c), in considering the available scientific evidence, including associated uncertainties, as it relates to the degree of public health protection provided by the current primary O_3 standard, the PA evaluates the extent to which health effects have been reported for the O_3 exposure concentrations evaluated in controlled human exposure studies and over the distributions of ambient O_3 concentrations in locations where epidemiologic studies have been conducted. The PA concludes that (1) the evidence from controlled human exposure studies provides strong support for the occurrence of adverse respiratory effects following exposures to O_3 concentrations below the level of the current standard and that (2) epidemiologic studies provide support for the occurrence of adverse respiratory effects and mortality under air quality conditions that would likely meet the current standard. In further considering the public health protection provided by the current standard, the PA next considers the results of exposure and health risk assessments.

2. Summary of Exposure- and Risk-Based Considerations in the PA

In order to further inform judgments about the potential public health implications of the current O_3 NAAQS, the PA considers the exposure and risk assessments presented in the HREA (U.S. EPA, 2014c, section 3.2). Overviews of these exposure and risk assessments, including summaries of key results and uncertainties, are provided in section II.C above. This section summarizes key observations from the PA related to the adequacy of the current O_3 NAAQS, based on consideration of the HREA exposure assessment (II.D.2.a), lung function risk assessment (II.D.2.b), and mortality/morbidity risk assessments (II.D.2.c).

a. Exposure Assessment—Key Observations

As discussed above (II.C.2), the exposure assessment provides estimates of the number and percent of people who would experience exposures of concern at or above benchmark concentrations of 60, 70, and 80 ppb. Benchmarks reflect exposure concentrations at which O_3-induced respiratory effects are known to occur in some healthy adults engaged in moderate, intermittent exertion, based on evidence from controlled human exposure studies (U.S. EPA, 2014c, section 3.1.2.1; U.S. EPA, 2013a, section 6.2).

The PA focuses on exposure estimates in children. Compared to recent (*i.e.,* unadjusted) air quality, the PA notes that adjusting air quality to just meet the current O_3 NAAQS consistently reduces the estimated occurrence of exposures of concern in children (U.S. EPA, 2014a, Appendix 5F). When averaged over the years evaluated in the HREA, reductions of up to about 70% were estimated. These reductions in estimated exposures of concern, relative to unadjusted air quality, reflect the consistent reductions in the highest ambient O_3 concentrations upon model adjustment to just meet the current standard (U.S. EPA, 2014c, section 3.2.1; U.S. EPA, 2014a, Chapter 4). Such reductions in estimated exposures of concern are evident throughout urban study areas, including in urban cores and in surrounding areas (U.S. EPA, 2014a, Appendix 9A).

Based on Figures 3–7 to 3–10 in the PA (U.S. EPA, 2014c), and the associated details described in the HREA (U.S. EPA, 2014a, Chapter 5), the PA further highlights key observations with regard to exposures of concern in children that are estimated to be allowed by the current standard. These key observations are summarized below for exposures of concern ≥60, 70, and 80 ppb.

For exposures of concern at or above 60 ppb, the PA highlights the following key observations for air quality adjusted to just meet the current standard:

(1) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 10 to 18% of children in urban study areas to experience one or more exposures of concern at or above 60 ppb. Summing across urban study areas, these percentages correspond to almost 2.5 million children experiencing approximately 4 million exposures of concern at or above 60 ppb during a single O_3 season. Of these children, almost 250,000 are asthmatics.[98]

(2) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 3 to 8% of children in urban study areas to experience two or more exposures of concern to O_3 concentrations at or above 60 ppb. Summing across the urban study areas, these percentages correspond to almost 900,000 children (including almost 90,000 asthmatic children) estimated to experience at least two O_3 exposure concentrations at or above 60 ppb during a single O_3 season.

(3) In the worst-case years (*i.e.,* those with the largest exposure estimates), the current standard is estimated to allow approximately 10 to 25% of children to experience one or more exposures of concern at or above 60 ppb, and approximately 4 to 14% to experience two or more exposures of concern at or above 60 ppb.

For exposures of concern at or above 70 ppb, the PA highlights the following key observations for air quality adjusted to just meet the current standard:

(1) On average over the years 2006 to 2010, the current standard is estimated to allow up to approximately 3% of children in urban study areas to experience one or more exposures of concern at or above 70 ppb. Summing across urban study areas, almost 400,000 children (including almost 40,000 asthmatic children) are estimated to experience O_3 exposure concentrations at or above 70 ppb during a single O_3 season.[99]

(2) On average over the years 2006 to 2010, the current standard is estimated to allow less than 1% of children in urban study areas to experience two or more exposures of concern to O_3 concentrations at or above 70 ppb.

(3) In the worst-case years, the current standard is estimated to allow approximately 1 to 8% of children to experience one or more exposures of concern at or above 70 ppb, and up to approximately 2% to experience two or more exposures of concern, at or above 70 ppb.

For exposures of concern at or above 80 ppb, the PA highlights the observation that the current standard is estimated to allow about 1% or fewer children in urban study areas to experience exposures of concern at or above 80 ppb, even in years with the highest exposure estimates.

b. Lung Function Risk Assessment—Key Observations

As discussed above (II.C.3.a), the HREA estimates risks of moderate to large lung function decrements (*i.e.,* FEV_1 decrements ≥10%, 15%, or 20%) in school-aged children (ages 5 to 18), asthmatic school-aged children, and the general adult population for 15 urban study areas. As for exposures of concern, the PA focuses on lung function risk estimates in children (including children with asthma).

Compared to risks associated with recent air quality, risk estimates for air quality just meeting the current standard are consistently smaller across urban study areas (U.S. EPA, 2014a, Appendix 6B). When averaged over the years evaluated in the HREA, risk reductions of up to about 40% were estimated compared to recent air quality. These reductions reflect the consistent decreases in relatively high ambient O_3 concentrations upon adjustment to just meet the current standard (U.S. EPA, 2014a, Chapter 4). Such reductions in estimated lung function risks are evident throughout urban study areas, including in urban cores and in surrounding areas (U.S. EPA, 2014, Appendix 9A).

Based on Figures 3–11 to 3–14 in the PA (U.S. EPA, 2014c), and the associated details described in the HREA (U.S. EPA, 2014a, chapter 6), the PA highlights key observations with regard to lung function risks estimated in children for air quality adjusted to just meet the current standard. These key observations are presented below for FEV_1 decrements ≥10, 15, and 20%.

With regard to decrements ≥10%, the PA highlights the following key observations for air quality adjusted to just meet the current standard:

[98] As discussed above (II.C.2.b), due to variability in responsiveness, only a subset of individuals who experience exposures at or above a benchmark concentration can be expected to experience adverse health effects.

[99] As discussed above (II.C.2.b), due to variability in responsiveness, only a subset of individuals who experience exposures at or above a benchmark concentration can be expected to experience adverse health effects.

(1) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 14 to 19% of children in urban study areas to experience one or more lung function decrements ≥10%. Summing across urban study areas, this corresponds to approximately 3 million children experiencing 15 million O_3-induced lung function decrements ≥10% during a single O_3 season. Of these children, about 300,000 are asthmatics.

(2) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 7 to 12% of children in urban study areas to experience two or more O_3-induced lung function decrements ≥10%. Summing across the urban study areas, this corresponds to almost 2 million children (including almost 200,000 asthmatic children) estimated to experience two or more O_3-induced lung function decrements greater than 10% during a single O_3 season.

(3) In the worst-case years, the current standard is estimated to allow approximately 17 to 23% of children in urban study areas to experience one or more lung function decrements ≥10%, and approximately 10 to 14% to experience two or more O_3-induced lung function decrements ≥10%.

With regard to decrements ≥15%, the PA highlights the following key observations for air quality adjusted to just meet the current standard:

(1) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 3 to 5% of children in urban study areas to experience one or more lung function decrements ≥15%. Summing across urban study areas, this corresponds to approximately 800,000 children (including approximately 80,000 asthmatic children) estimated to experience at least one O_3-induced lung function decrement ≥15% during a single O_3 season.

(2) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 2 to 3% of children in urban study areas to experience two or more O_3-induced lung function decrements ≥15%.

(3) In the worst-case years, the current standard is estimated to allow approximately 4 to 6% of children in urban study areas to experience one or more lung function decrements ≥15%, and approximately 2 to 4% to experience two or more O_3-induced lung function decrements ≥15%.

With regard to decrements ≥20%, the PA highlights the following key observations for air quality adjusted to just meet the current standard:

(1) On average over the years 2006 to 2010, the current standard is estimated to allow approximately 1 to 2% of children in urban study areas to experience one or more lung function decrements ≥20%. Summing across urban study areas, this corresponds to approximately 300,000 children (including approximately 30,000 asthmatic children) estimated to experience at least one O_3-induced lung function decrement ≥20% during a single O_3 season.

(2) On average over the years 2006 to 2010, the current standard is estimated to allow less than 1% of children in urban study areas to experience two or more O_3-induced lung function decrements ≥20%.

(3) In the worst-case years, the current standard is estimated to allow approximately 2 to 3% of children to experience one or more lung function decrements ≥20%, and less than 2% to experience two or more O_3-induced lung function decrements ≥20%.

c. Mortality and Morbidity Risk Assessments—Key Observations

As discussed above (II.C.3.b), risk estimates based on epidemiologic studies can provide perspective on the most serious O_3-associated public health outcomes (*e.g.,* mortality, hospital admissions, emergency department visits) in populations that often include at-risk groups. The HREA estimates such O_3-associated risks in 12 urban study areas [100] using concentration-response relationships drawn from epidemiologic studies. These concentration-response relationships are based on ''area-wide'' average O_3 concentrations.[101] The HREA estimates risks for the years 2007 and 2009 in order to provide estimates of risk for a year with generally higher O_3 concentrations (2007) and a year with generally lower O_3 concentrations (2009) (U.S. EPA, 2014a, section 7.1.1).

In considering these estimates, the PA notes that HREA conclusions reflect somewhat lower confidence in epidemiologic-based risk estimates than in estimates of O_3 exposures of concern and O_3-induced lung function decrements (U.S. EPA, 2014a, section 9.6). In particular, the HREA highlights the unexplained heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions at lower O_3 concentrations (U.S. EPA, 2014a, section 9.6). The HREA also concludes that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study, though that study is well-designed, and because of the uncertainty in that study about the existence and identification of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6). These and other uncertainties are considered in the PA in reaching conclusions on the current and alternative standards (U.S. EPA, 2014c, sections 3.4, 4.6).

Key observations from the PA are summarized below for mortality and morbidity risks associated with air quality adjusted to simulate just meeting the current O_3 NAAQS. These include key observations for estimates of total (nonaccidental) mortality associated with short-term O_3 concentrations, respiratory morbidity associated with short-term O_3 concentrations, and respiratory mortality associated with long-term O_3 concentrations (U.S. EPA, 2014c, section 3.2.3.2).

With regard to total mortality or morbidity associated with short-term O_3, the PA notes the following for air quality adjusted to just meet the current standard:

(1) When air quality was adjusted to the current standard for the 2007 model year (the year with generally ''higher'' O_3-associated risks), 10 of 12 urban study areas exhibited either decreases or virtually no change in estimates of the number of O_3-associated deaths (U.S. EPA, 2014a, Appendix 7B). Increases were estimated in two of the urban

[100] The 12 urban areas evaluated are Atlanta, Baltimore, Boston, Cleveland, Denver, Detroit, Houston, Los Angeles, New York, Philadelphia, Sacramento, and St. Louis. Morbidity endpoints were evaluated in subsets of these areas, based on availability of appropriate studies (U.S. EPA, 2014a, Chapter 7).

[101] In the epidemiologic studies that provide the health basis for HREA risk assessments, concentration-response relationships are based on daytime O_3 concentrations, averaged across multiple monitors within study areas. These daily averages are used as surrogates for the spatial and temporal patterns of exposures in study populations. Consistent with this approach, the HREA epidemiologic-based risk estimates also utilize daytime O_3 concentrations, averaged across monitors, as surrogates for population exposures. In this notice, these averaged concentrations are referred to as ''area-wide'' O_3 concentrations. Area-wide concentrations are discussed in more detail in section 3.1.4 of the PA (U.S. EPA, 2014c).

study areas (Houston, Los Angeles)[102] (U.S. EPA, 2014a, Appendix 7B).[103]

(2) In focusing on total risk, the current standard is estimated to allow thousands of O_3-associated deaths per year in the urban study areas. In focusing on the risks associated with the upper portions of distributions of ambient concentrations (area-wide concentrations ≥40, 60 ppb), the current standard is estimated to allow hundreds to thousands of O_3-associated deaths per year in the urban study areas.

(3) The current standard is estimated to allow tens to thousands of O_3-associated morbidity events per year (*i.e.,* respiratory-related hospital admissions, emergency department visits, and asthma exacerbations).

With regard to respiratory mortality associated with long-term O_3, the PA notes the following for air quality adjusted to just meet the current standard:

(1) Based on a linear concentration-response function, the current standard is estimated to allow thousands of O_3-associated respiratory deaths per year in the urban study areas.

(2) Based on threshold models, HREA sensitivity analyses indicate that the number of respiratory deaths associated with long-term O_3 concentrations could potentially be considerably lower (*i.e.,* by more than 75% if a threshold exists at 40 ppb, and by about 98% if a threshold exists at 56 ppb) (U.S. EPA, 2014a, Figure 7–9).[104]

[102] As discussed above (II.C.1), in locations and time periods when NO_X is predominantly contributing to O_3 formation (*e.g.,* downwind of important NO_X sources, where the highest O_3 concentrations often occur), model-based adjustment to the current and alternative standards decreases estimated ambient O_3 concentrations compared to recent monitored concentrations (U.S. EPA, 2014a, section 4.3.3.2). In contrast, in locations and time periods when NO_X is predominantly contributing to O_3 titration (*e.g.,* in urban centers with high concentrations of NO_X emissions, where ambient O_3 concentrations are often suppressed and thus relatively low), model-based adjustment increases ambient O_3 concentrations compared to recent monitored concentrations (U.S. EPA, 2014a, section 4.3.3.2). Changes in epidemiology-based risk estimates depend on the balance between the daily decreases in high O_3 concentrations and increases in low O_3 concentrations following the model-based air quality adjustment. Commenting on this issue, CASAC noted that ''controls designed to reduce the peak levels of ozone (*e.g.,* the 4th highest annual MDA8) may not be effective at reducing lower levels of ozone on more typical days and may actually increase ozone levels on days where ozone concentrations are low'' (Frey 2014a, p. 2). CASAC further noted that risk results ''suggest that the ozone-related health risks in the urban cores can increase for some of the cities as ozone NAAQS alternatives become more stringent. This is because reductions in nitrogen oxides emissions can lead to less scavenging of ozone and free radicals, resulting in locally higher levels of ozone'' (Frey 2014c, p. 10).

[103] For the 2009 adjusted year (*i.e.,* the year with generally lower O_3 concentrations), changes in risk were generally smaller than in 2007 (*i.e.,* most changes about 2% or smaller). Increases were estimated for Houston, Los Angeles, and New York City.

[104] Risk estimates for respiratory mortality associated with long-term O_3 exposures are based on the study by Jerrett et al. (2009) (U.S. EPA, 2014a, Chapter 7). As discussed above (II.B.2.b.iv) and in the PA (U.S. EPA, 2014c, section 3.1.4.3), Jerrett et al. (2009) reported that when seasonal averages of 1-hour daily maximum O_3 concentrations ranged from 33 to 104 ppb, there was no statistical deviation from a linear concentration-response relationship between O_3 and respiratory mortality across 96 U.S. cities (U.S. EPA, 2013a, section 7.7). However, the authors reported ''limited evidence'' for an effect threshold at an O_3 concentration of 56 ppb (p=0.06). In communications with EPA staff (Sasser, 2014), the study authors indicated that it is not clear whether a threshold model is a better predictor of respiratory mortality than the linear model, and that ''considerable caution should be exercised in accepting any specific threshold.''

3. Policy Assessment Conclusions on the Current Standard

As an initial matter, the PA concludes that reducing precursor emissions to achieve O_3 concentrations that meet the current standard will provide important improvements in public health protection. This initial conclusion is based on (1) the strong body of scientific evidence indicating a wide range of adverse health outcomes attributable to exposures to O_3 concentrations commonly found in the ambient air and (2) estimates indicating decreased occurrences of O_3 exposures of concern and decreased health risks upon meeting the current standard, compared to recent air quality.

In particular, the PA concludes that strong support for this initial conclusion is provided by controlled human exposure studies of respiratory effects, and by quantitative estimates of exposures of concern and lung function decrements based on information in these studies. Analyses in the HREA estimate that the percentages of children (*i.e.,* all children and children with asthma) in urban study areas experiencing exposures of concern, or experiencing abnormal and potentially adverse lung function decrements, are consistently lower for air quality that just meets the current O_3 standard than for recent air quality. The HREA estimates such reductions consistently across the urban study areas evaluated and throughout various portions of individual urban study areas, including in urban cores and the portions of urban study areas surrounding urban cores. These reductions in exposures of concern and O_3-induced lung function decrements reflect the consistent decreases in the highest O_3 concentrations following reductions in precursor emissions to meet the current standard. Thus, populations in both urban and non-urban areas would be expected to experience important reductions in O_3 exposures and O_3-induced lung function risks upon meeting the current standard.[105]

The PA further concludes that support for this initial conclusion is also provided by estimates of O_3-associated mortality and morbidity based on application of concentration-response relationships from epidemiologic studies to air quality adjusted to just meet the current standard. These estimates, which are based on the assumption that concentration-response relationships are linear over entire distributions of ambient O_3 concentrations, are associated with uncertainties that complicate their interpretation (II.C.3). However, risk estimates for effects associated with short- and long-term O_3 exposures, combined with the HREA's national analysis of O_3 responsiveness to reductions in precursor emissions and the consistent reductions estimated for the highest ambient O_3 concentrations, suggest that O_3-associated mortality and morbidity would be expected to decrease nationwide following reductions in precursor emissions to meet the current O_3 standard.

Reductions in O_3 precursor emissions (*i.e.,* NO_X) could also increase public health protection by reducing the ambient concentrations of pollutants other than O_3. For example, in their advice on the second draft HREA CASAC acknowledged the potential for ambient NO_2 concentrations to be affected by changes in NO_X emissions (Frey, 2014a, p. 10). Consistent with this, the PA notes that NO_X emissions contribute to ambient NO_2, and that NO_X and VOCs can contribute to secondary formation of $PM_{2.5}$ constituents, including ammonium sulfate (NH_4SO_4), ammonium nitrate (NH_4NO_3), and organic carbon (OC). Therefore, at some times and in some locations, control strategies that would reduce NO_X emissions (*i.e.,* to meet an O_3 standard) could reduce ambient concentrations of NO_2 and $PM_{2.5}$, resulting in health benefits beyond those directly associated with reducing ambient O_3 concentrations.

After reaching the initial conclusion that meeting the current primary O_3 standard will provide important improvements in public health protection, and that it is not appropriate to consider a standard that is less protective than the current standard, the PA considers the adequacy of the public health protection that is provided by the

[105] As discussed above (II.C.1), CASAC recommended that the EPA evaluate how health risks in urban centers, as well as outside urban centers, change upon reducing NO_X emissions, given the varying impacts of NO_X emissions reductions on ambient O_3 concentrations.

current standard. In considering the available scientific evidence, exposure/risk information, advice from CASAC (II.D.4, below), and input from the public, the PA reaches the conclusion that the available evidence and information clearly call into question the adequacy of public health protection provided by the current primary standard. In reaching this conclusion, the PA notes that evidence from controlled human exposure studies provides strong support for the occurrence of adverse respiratory effects following exposures to O_3 concentrations below the level of the current standard. Epidemiologic studies provide support for the occurrence of adverse respiratory effects and mortality under air quality conditions that would likely meet the current standard. In addition, based on the analyses in the HREA, the PA concludes that the exposures and risks projected to remain upon meeting the current standard are indicative of risks that can reasonably be judged to be important from a public health perspective. Thus, the PA concludes that the evidence and information provide strong support for giving consideration to revising the current primary standard in order to provide increased public health protection against an array of adverse health effects that range from decreased lung function and respiratory symptoms to more serious indicators of morbidity (*e.g.,* including emergency department visits and hospital admissions), and mortality. In consideration of all of the above, the PA draws the conclusion that it is appropriate for the Administrator to consider revision of the current primary O_3 standard to provide increased public health protection.

4. CASAC Advice

Following the 2008 decision to revise the primary O_3 standard by setting the level at 0.075 ppm (75 ppb), CASAC strongly questioned whether the standard met the requirements of the CAA. In September 2009, the EPA announced its intention to reconsider the 2008 standards, issuing a notice of proposed rulemaking in January 2010 (75 FR 2938). Soon after, the EPA solicited CASAC review of that proposed rule and in January 2011, solicited additional advice. This proposal was based on the scientific and technical record from the 2008 rulemaking, including public comments and CASAC advice and recommendations. As further described above (I.C), in the fall of 2011, the EPA did not revise the standard as part of the reconsideration process but decided to defer decisions on revisions to the O_3 standards to the next periodic review, which was already underway. Accordingly, in this section we describe CASAC's advice related to the 2008 final decision and the subsequent reconsideration, as well as its advice on this current review of the O_3 NAAQS that was initiated in September 2008.

In April 2008, the members of the CASAC Ozone Review Panel sent a letter to EPA stating ''[I]n our most-recent letters to you on this subject—dated October 2006 and March 2007—the CASAC unanimously recommended selection of an 8-hour average Ozone NAAQS within the range of 0.060 to 0.070 parts per million [60 to 70 ppb] for the primary (human health-based) Ozone NAAQS'' (Henderson, 2008). The letter continued:

> The CASAC now wishes to convey, by means of this letter, its additional, unsolicited advice with regard to the primary and secondary Ozone NAAQS. In doing so, the participating members of the CASAC Ozone Review Panel are unanimous in strongly urging you or your successor as EPA Administrator to ensure that these recommendations be considered during the next review cycle for the Ozone NAAQS that will begin next year . . . numerous medical organizations and public health groups have also expressed their support of these CASAC recommendations' . . . [The CASAC did] not endorse the new primary ozone standard as being sufficiently protective of public health. The CASAC—as the EPA's statutorily-established science advisory committee for advising you on the national ambient air quality standards—unanimously recommended decreasing the primary standard to within the range of 0.060–0.070 ppm [60 to 70 ppb]. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations.

In response to the EPA's solicitation of advice on the EPA's proposed rulemaking as part of the reconsideration, CASAC conveyed support (Samet, 2010).

> CASAC fully supports EPA's proposed range of 0.060–0.070 parts per million (ppm) for the 8-hour primary ozone standard. CASAC considers this range to be justified by the scientific evidence as presented in the Air Quality Criteria for Ozone and Related Photochemical Oxidants (March 2006) and Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper (July 2007). As stated in our letters of October 24, 2006, March 26, 2007 and April 7, 2008 to former Administrator Stephen L. Johnson, CASAC unanimously recommended selection of an 8-hour average ozone NAAQS within the range proposed by EPA (0.060 to 0.070 ppm). In proposing this range, EPA has recognized the large body of data and risk analyses demonstrating that retention of the current standard would leave large numbers of individuals at risk for respiratory effects and/or other significant health impacts including asthma exacerbations, emergency room visits, hospital admissions and mortality.

In response to EPA's request for additional advice on the reconsideration in 2011, CASAC reaffirmed their conclusion that ''the evidence from controlled human and epidemiological studies strongly supports the selection of a new primary ozone standard within the 60–70 ppb range for an 8-hour averaging time'' (Samet, 2011, p ii). As requested by the EPA, CASAC's advice and recommendations were based on the scientific and technical record from the 2008 rulemaking. In considering the record for the 2008 rulemaking, CASAC stated the following to summarize the basis for their conclusions (Samet, 2011, pp. ii to iii).

(1) The evidence available on dose-response for effects of O_3 shows associations extending to levels within the range of concentrations currently experienced in the United States.

(2) There is scientific certainty that 6.6-hour exposures with exercise of young, healthy, non-smoking adult volunteers to concentrations ≥80 ppb cause clinically relevant decrements of lung function.

(3) Some healthy individuals have been shown to have clinically relevant responses, even at 60 ppb.

(4) Since the majority of clinical studies involve young, healthy adult populations, less is known about health effects in such potentially ozone sensitive populations as the elderly, children and those with cardiopulmonary disease. For these susceptible groups, decrements in lung function may be greater than in healthy volunteers and are likely to have a greater clinical significance.

(5) Children and adults with asthma are at increased risk of acute exacerbations on or shortly after days when elevated O_3 concentrations occur, even when exposures do not exceed the NAAQS concentration of 75 ppb.

(6) Large segments of the population fall into what the EPA terms a ''sensitive population group,'' *i.e.,* those at increased risk because they are more intrinsically susceptible (children, the elderly, and individuals with chronic lung disease) and those who are more vulnerable due to increased exposure because they work outside or live in areas that are more polluted than the mean levels in their communities.

With respect to evidence from epidemiologic studies, CASAC stated ''while epidemiological studies are

inherently more uncertain as exposures and risk estimates decrease (due to the greater potential for biases to dominate small effect estimates), specific evidence in the literature does not suggest that our confidence on the specific attribution of the estimated effects of ozone on health outcomes differs over the proposed range of 60–70 ppb'' (Samet, 2011, p. 10).

Following its review of the second draft PA in the current review, which considers an updated scientific and technical record since the 2008 rulemaking, CASAC concluded that ''there is clear scientific support for the need to revise the standard'' (Frey, 2014c, p. ii). In particular, CASAC noted the following (Frey, 2014c, p. 5):

> [T]he scientific evidence provides strong support for the occurrence of a range of adverse respiratory effects and mortality under air quality conditions that would meet the current standard. Therefore, CASAC unanimously recommends that the Administrator revise the current primary ozone standard to protect public health.[106]

In supporting these conclusions, CASAC judged that the strongest evidence comes from controlled human exposure studies of respiratory effects. The Committee specifically noted that ''the combination of decrements in FEV_1 together with the statistically significant alterations in symptoms in human subjects exposed to 72 ppb ozone meets the American Thoracic Society's definition of an adverse health effect'' (Frey, 2014c, p. 5). CASAC further judged that ''if subjects had been exposed to ozone using the 8-hour averaging period used in the standard, adverse effects could have occurred at lower concentration'' and that ''the level at which adverse effects might be observed would likely be lower for more sensitive subgroups, such as those with asthma'' (Frey, 2014c, p. 5).

With regard to lung function risk estimates based on information from controlled human exposure studies, CASAC concluded that ''estimation of FEV_1 decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV1 decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease'' (Frey, 2014c, p. 3). The Committee further concluded that ''[a]sthmatic subjects appear to be at least as sensitive, if not more sensitive, than non-asthmatic subjects in manifesting O_3-induced pulmonary function decrements'' (Frey, 2014c, p. 4). In considering estimates of the occurrence of these decrements in urban study areas, CASAC specifically noted that the current standard is estimated to allow 11 to 22% of school age children to experience at least one day with an FEV_1 decrement ≥10% (Frey, 2014c, p. 7).

Although CASAC judged that controlled human exposure studies of respiratory effects provide the strongest evidence supporting their conclusion on the current standard, the Committee judged that there is also ''sufficient scientific evidence based on epidemiologic studies for mortality and morbidity associated with short-term exposure to ozone at the level of the current standard'' (Frey, 2014c, p. 5). In support of the biological plausibility of the associations reported in these epidemiologic studies, CASAC noted that ''[r]ecent animal toxicological studies support identification of modes of action and, therefore, the biological plausibility associated with the epidemiological findings'' (Frey, 2014c, p. 5).

Consistent with the advice of CASAC, several public commenters supported revising the primary O_3 standard to provide increased public health protection. In considering the available evidence as a basis for their views, these commenters generally noted that the health evidence is stronger in the current review than in past reviews, with new evidence for effects attributable to short- and long-term exposures, and new evidence for effects at lower O_3 exposure concentrations.

Other public commenters opposed considering revised standards. These commenters discussed a variety of reasons for their views. A number of commenters expressed the view that the EPA should not lower the level of the standard because a lower level would be closer to background O_3 concentrations. In addition, several commenters challenged the interpretation of the evidence presented in the ISA. With respect to the risk assessment, several commenters expressed the view that the EPA should only estimate risks above O_3 background concentrations, or above threshold concentrations. Some commenters also expressed the view that, based on the mortality and morbidity risk estimates in the HREA, there is little to no difference between the risks estimated for the current O_3 standard and the risks estimated for revised standards with lower levels. These commenters concluded that the HREA and PA have not shown that the public health improvements likely to be achieved by a revised O_3 standard would be greater than the improvements likely to be achieved by the current standard.

5. Administrator's Proposed Conclusions Concerning the Adequacy of the Current Standard

This section discusses the Administrator's proposed conclusions related to the adequacy of the public health protection provided by the current primary O_3 standard, resulting in her proposed decision to revise that standard. These proposed conclusions, and her proposed decision, are based on the Administrator's consideration of the available scientific evidence, exposure/risk information, the comments and advice of CASAC, and public input received thus far, as summarized below.

As an initial matter, the Administrator concludes that reducing precursor emissions to achieve O_3 concentrations that meet the current primary O_3 standard will provide important improvements in public health protection, compared to recent air quality. In reaching this initial conclusion, she notes the discussion in section 3.4 of the PA (U.S. EPA, 2014c), summarized above (II.D.3). In particular, the Administrator notes that this initial conclusion is supported by (1) the strong body of scientific evidence indicating a wide range of adverse health outcomes attributable to exposures to O_3 at concentrations commonly found in the ambient air and (2) estimates indicating decreased occurrences of O_3 exposures of concern and decreased O_3-associated health risks upon meeting the current standard, compared to recent air quality. Thus, she concludes that it would not be appropriate in this review to consider a standard that is less protective than the current standard.[107]

After reaching the initial conclusion that meeting the current primary O_3 standard will provide important improvements in public health protection, and that it is not appropriate to consider a standard that is less protective than the current standard, the Administrator next considers the adequacy of the public health protection that is provided by the current standard. In doing so, the Administrator first notes that studies evaluated since the completion of the 2006 O_3 AQCD

[106] CASAC provided similar advice in their letter to the Administrator on the REA, stating that ''The CASAC finds that the current primary NAAQS for ozone is not protective of human health and needs to be revised'' (Frey, 2014a, p. 15).

[107] While not analyzed quantitatively, consistent with CASAC advice (Frey, 2014a, p. 10), the Administrator notes that reductions in O_3 precursor emissions (*e.g.,* NO_X; VOC) to achieve O_3 concentrations that meet the current standard could also increase public health protection by reducing the ambient concentrations of pollutants other than O_3 (*i.e.,* $PM_{2.5}$, NO_2).

support and expand upon the strong body of evidence that, in the last review, indicated a causal relationship between short-term O_3 exposures and respiratory health effects. This is the strongest causality finding possible under the ISA's hierarchical system for classifying weight of evidence for causation. Together, experimental and epidemiologic studies support conclusions regarding a continuum of O_3 respiratory effects ranging from small reversible changes in pulmonary function, and pulmonary inflammation, to more serious effects that can result in respiratory-related emergency department visits, hospital admissions, and premature mortality. Recent animal toxicology studies support descriptions of modes of action for these respiratory effects and augment support for biological plausibility for the role of O_3 in reported effects. With regard to mode of action, evidence indicates that antioxidant capacity may modify the risk of respiratory morbidity associated with O_3 exposure, and that the inherent capacity to quench (based on individual antioxidant capacity) can be overwhelmed, especially with exposure to elevated concentrations of O_3. In addition, based on the consistency of findings across studies and evidence for the coherence of results from different scientific disciplines, evidence indicates that certain populations are at increased risk of experiencing O_3-related effects, including the most severe effects. These include populations and lifestages identified in previous reviews (*i.e.,* people with asthma, children, older adults, outdoor workers) and populations identified since the last review (*i.e.,* people with certain genotypes related to antioxidant and/or anti-inflammatory status; people with reduced intake of certain antioxidant nutrients, such as Vitamins C and E).

The Administrator further notes that evidence for adverse respiratory health effects attributable to long-term, or repeated short-term, O_3 exposures is much stronger than in previous reviews, and the ISA concludes that there is ''likely to be'' a causal relationship between such O_3 exposures and adverse respiratory health effects (the second strongest causality finding). Uncertainties related to the extrapolation of data generated by rodent toxicology studies to the understanding of health effects in humans have been reduced by studies in non-human primates and by recent epidemiologic studies. The evidence available in this review includes new epidemiologic studies using a variety of designs and analysis methods, conducted by different research groups in different locations, evaluating the relationships between long-term O_3 exposures and measures of respiratory morbidity and mortality. New evidence supports associations between long-term O_3 exposures and the development of asthma in children, with several studies reporting interactions between genetic variants and such O_3 exposures. Studies also report associations between long-term O_3 exposures and asthma prevalence, asthma severity and control, respiratory symptoms among asthmatics, and respiratory mortality.

In considering the O_3 exposure concentrations reported to elicit respiratory effects, the Administrator agrees with the conclusions of the PA and with the advice of CASAC (Frey, 2014c) that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following exposures to specific O_3 concentrations. In particular, as discussed further in section II.E.4.d below, she notes that the effects reported in controlled human exposure studies are due solely to O_3 exposures, and interpretation of study results is not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies). Therefore, she places the most weight on information from these controlled human exposure studies.

In considering the evidence from controlled human exposure studies, the Administrator first notes that these studies have reported a variety of respiratory effects in healthy adults following exposures to O_3 concentrations of 60, 72,[108] or 80 ppb, and higher. The largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures of healthy adults to 80 ppb O_3 or higher, with most exposure studies conducted at these higher concentrations. She further notes that recent evidence includes controlled human exposure studies reporting the combination of lung function decrements and respiratory symptoms in healthy adults engaged in intermittent, moderate exertion following 6.6 hour exposures to concentrations as low as 72 ppb, and lung function decrements and pulmonary inflammation following exposures to O_3 concentrations as low as 60 ppb. As discussed below, compared to the evidence available in the last review, these studies have strengthened support for the occurrence of abnormal and adverse respiratory effects attributable to short-term exposures to O_3 concentrations below the level of the current standard.[109] The Administrator concludes that such exposures to O_3 concentrations below the level of the current standard are potentially important from a public health perspective, given the following:

(1) The combination of lung function decrements and respiratory symptoms reported to occur in healthy adults following exposures to 72 ppb O_3 or higher, while at moderate exertion, meet ATS criteria for an adverse response. In specifically considering the 72 ppb exposure concentration, CASAC noted that ''the combination of decrements in FEV_1 together with the statistically significant alterations in symptoms in human subjects exposed to 72 ppb ozone meets the American Thoracic Society's definition of an adverse health effect'' (Frey, 2014c, p. 5).

(2) With regard to 60 ppb O_3, CASAC agreed that ''a level of 60 ppb corresponds to the lowest exposure concentration demonstrated to result in lung function decrements large enough to be judged an abnormal response by ATS and that could be adverse in individuals with lung disease'' (Frey, 2014c, p. 7). CASAC further noted that ''a level of 60 ppb also corresponds to the lowest exposure concentration at which pulmonary inflammation has been reported'' (Frey, 2014c, p. 7).

(3) The controlled human exposure studies reporting these respiratory effects were conducted in healthy adults, while at-risk groups (*e.g.,* children, people with asthma) could experience larger and/or more serious effects. In their advice to the Administrator, CASAC concurred with this reasoning (Frey, 2014a, p. 14; Frey, 2014c, p. 5).

(4) These respiratory effects are coherent with the serious health outcomes that have been reported in epidemiologic studies evaluating exposure to O_3 (*e.g.,* respiratory-related hospital admissions, emergency department visits, and mortality).

As noted above, the Administrator's proposed conclusions regarding the adequacy of the current primary O_3 standard place a large amount of weight on the results of controlled human exposure studies. In particular, given the combination of lung function

[108] As noted above, for the 70 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual mean exposure concentration was 72 ppb.

[109] Cf. *State of Misisssippi.* 744 F.3d 1350 (''Perhaps more studies like the Adams studies will yet reveal that the 0.060 ppm level produces significant adverse decrements that simply cannot be attributed to normal variation in lung function.'').

decrements and respiratory symptoms following 6.6 hour exposures to O_3 concentrations as low as 72 ppb, and given CASAC advice regarding effects at 72 ppb along with ATS adversity criteria, she concludes that the evidence in this review supports the occurrence of adverse respiratory effects following exposures to O_3 concentrations lower than the level of the current standard.[110] As discussed below, the Administrator further considers information from the broader body of controlled human exposure studies within the context of quantitative estimates of exposures of concern and O_3-induced FEV_1 decrements.

In addition to controlled human exposure studies, the Administrator also considers what the available epidemiologic evidence indicates with regard to the adequacy of the public health protection provided by the current primary O_3 standard.[111] She notes that recent epidemiologic studies provide support, beyond that available in the last review, for associations between short-term O_3 exposures and a wide range of adverse respiratory outcomes (including respiratory-related hospital admissions, emergency department visits, and mortality) and with total mortality. Associations with morbidity and mortality are stronger during the warm or summer months, and remain robust after adjustment for copollutants.

In considering information from epidemiologic studies within the context of her conclusions on the adequacy of the current standard, the Administrator considers the extent to which available studies support the occurrence of O_3 health effect associations with air quality likely to be allowed by the current standard. In doing so, she places the most weight on air quality analyses in locations of single-city studies of short-term O_3, as discussed in more detail in section II.E.4.d below.[112] In particular, she notes that a U.S. single-city study reported associations with respiratory emergency department visits in children and adults in a location that would likely have met the current O_3 standard over the entire study period (Mar and Koenig, 2009). In addition, even in some single-city study locations where the current standard was likely not met (*i.e.,* Silverman and Ito, 2010; Strickland et al., 2010), the Administrator notes PA analyses indicating that reported concentration-response functions and available air quality data support the occurrence of O_3-health effect associations on subsets of days with ambient O_3 concentrations below the level of the current standard (II.D.1). Compared to single-city studies, the Administrator notes additional uncertainty in interpreting the relationships between air quality in individual study cities and health effects based on multicity analyses (discussed further in sections II.D.1 and II.E.4.d). While such uncertainties limit the extent to which the Administrator bases her conclusions on air quality in locations of multicity epidemiologic studies, she does note that O_3 associations with respiratory morbidity or mortality have been reported in several multicity studies when the majority of study locations (though not all study locations) would likely have met the current O_3 standard. When taken together, the Administrator reaches the conclusion that single-city epidemiologic studies and associated air quality information support the occurrence of O_3-associated hospital admissions and emergency department visits for ambient O_3 concentrations likely to have met the current standard, and that air quality analyses in locations of multicity studies provide some support for this conclusion for a broader range of effects (*i.e.,* including mortality).

Beyond her consideration of the scientific evidence, the Administrator also considers the results of the HREA exposure and risk analyses in reaching initial conclusions regarding the adequacy of the current primary O_3 standard. In doing so, as noted above, she focuses primarily on exposure and risk estimates based on information from controlled human exposure studies (*i.e.,* exposures of concern and O_3-induced lung function decrements). She places relatively less weight on epidemiologic-based risk estimates, noting that the overall conclusions from the HREA likewise reflect less confidence in estimates of epidemiologic-based risks than in estimates of exposures and lung function risks (U.S. EPA, 2014, section 9.6). Consistent with the conclusions in the PA, her determination to attach less weight to the epidemiologic-based risk estimates reflects her consideration of key uncertainties, including the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions for O_3 concentrations in the lower portions of ambient distributions (U.S. EPA, 2014, section 9.6) (II.D.2). In particular, she concludes that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study (even though that study is well-designed) and because of the uncertainty in that study about the existence and level of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6) (II.D.2).[113]

With regard to estimates of exposures of concern, the Administrator considers the extent to which the current standard provides protection against exposures to O_3 concentrations at or above 60, 70, and 80 ppb, noting CASAC advice that 60 ppb ''is an appropriate exposure of concern for asthmatic children'' (Frey, 2014c, p. 8). She further notes that while single exposures of concern could be adverse for some people, particularly for the higher benchmark concentrations (70, 80 ppb) where there is stronger evidence for the occurrence of adverse effects (discussed further in II.E.4.d, below), she becomes increasingly concerned about the potential for adverse responses as the frequency of occurrences increases.[114] In particular,

[110] The use of evidence from controlled human exposure studies conducted in healthy adults to characterize the potential for adverse effects, including in at-risk groups such as children and asthmatics, is discussed in sections II.C.2 and II.C.3.a, above. CASAC advice on this issue is discussed in sections II.D.4 and II.E.4.c.

[111] As noted above, she places less weight on information from epidemiologic studies than on information from controlled human exposure studies.

[112] As discussed in section II.E.4.d of this preamble, this judgment applies specifically to epidemiologic studies of short-term O_3 concentrations where multicity effect estimates are presented, based on combining the effect estimates from multiple individual cities, and where individual city effect estimates are not presented (as is the case for key multicity studies analyzed in the PA). Because these reported multicity effect estimates do not allow health effect associations to be disaggregated by individual city, it is not possible to assign the health effect association to the air quality in any one study location, or to the air quality in a subset of locations. In contrast, for epidemiologic studies of long-term concentrations, where multicity effect estimates are based on comparisons across cities, different judgments have been made with regard to the utility of multicity studies (see, *e.g.* 78 FR 3086 at 3103/2) (January 15, 2013) (and see discussion below of study by Jerrett et al., (2009)).

[113] CASAC also called into question the extent to which it is appropriate to place confidence in risk estimates for respiratory mortality (Frey, 2014a, p. 11).

[114] Not all people who experience an exposure of concern will experience an adverse effect (even members of at-risk populations). For most of the endpoints evaluated in controlled human exposure studies (with the exception of O_3-induced FEV_1 decrements, as discussed below), the number of those experiencing exposures of concern who will experience adverse effects cannot be reliably quantified.

she notes that repeated occurrences of the types of effects shown to occur following exposures of concern can have potentially adverse outcomes. For example, repeated occurrences of airway inflammation could potentially result in the induction of a chronic inflammatory state; altered pulmonary structure and function, leading to diseases such as asthma; altered lung host defense response to inhaled microorganisms; and altered lung response to other agents such as allergens or toxins (U.S. EPA, 2013a, section 6.2.3). Thus, the Administrator notes that the types of lung injury shown to occur following exposures to O_3 concentrations from 60 to 80 ppb, particularly if experienced repeatedly, provide a mode of action by which O_3 may cause other more serious effects (*e.g.,* asthma exacerbations). Therefore, the Administrator places the most weight on estimates of two or more exposures of concern (*i.e.,* as a surrogate for the occurrence of repeated exposures), though she also considers estimates of one or more, particularly for the 70 and 80 ppb benchmarks.

Consistent with CASAC advice (Frey, 2014c), the Administrator focuses on children in these analyses of O_3 exposures, noting that estimates for all children and asthmatic children are virtually indistinguishable (in terms of the percent estimated to experience exposures of concern). Though she focuses on children, she also recognizes that exposures to O_3 concentrations at or above 60 or 70 ppb could be of concern for adults. As discussed in the HREA and PA (and II.C.2.a, above), the patterns of exposure estimates across urban study areas, across years, and across air quality scenarios are similar in adults with asthma, older adults, all children, and children with asthma, though smaller percentages of adult populations are estimated to experience exposures of concern than children and children with asthma. Thus, the Administrator recognizes that the exposure patterns for children across years, urban study areas, and air quality scenarios are indicative of the exposure patterns in a broader group of at-risk populations that also includes asthmatic adults and older adults.

As illustrated in Table 1 (above), the Administrator notes that if the 15 urban study areas evaluated in the HREA were to just meet the current O_3 standard, fewer than 1% of children in those areas would be estimated to experience two or more exposures of concern at or above 70 ppb, though approximately 3 to 8% of children, including approximately 3 to 8% of asthmatic children, would be estimated to experience two or more exposures of concern to O_3 concentrations at or above 60 ppb [115] (based on estimates averaged over the years of analysis). To provide some perspective on these percentages, the Administrator notes that they correspond to almost 900,000 children in urban study areas, including about 90,000 asthmatic children, estimated to experience two or more exposures of concern at or above 60 ppb. Nationally, if the current standard were to be just met the number of children experiencing such exposures would be larger. In the worst-case year and location (*i.e.,* year and location with the largest exposure estimates), the Administrator notes that over 2% of children are estimated to experience two or more exposures of concern at or above 70 ppb and over 14% are estimated to experience two or more exposures of concern at or above 60 ppb.

Although, as discussed above and in section II.E.4.d, the Administrator is less concerned about single occurrences of exposures of concern, she notes that even single occurrences can cause adverse effects in some people, particularly for the 70 and 80 ppb benchmarks. Therefore, she also considers estimates of one or more exposures of concern. As illustrated in Table 1 (above), if the 15 urban study areas evaluated in the HREA were to just meet the current O_3 standard, fewer than 1% of children in those areas would be estimated to experience one or more exposures of concern at or above 80 ppb (based on estimates averaged over the years of analysis). However, approximately 1 to 3% of children, including 1 to 3% of asthmatic children, would be estimated to experience one or more exposures of concern to O_3 concentrations at or above 70 ppb and approximately 10 to 17% would be estimated to experience one or more exposures of concern to O_3 concentrations at or above 60 ppb. In the worst-case year and location, the Administrator notes that over 1% of children are estimated to experience one or more exposures of concern at or above 80 ppb, over 8% are estimated to experience one or more exposures of concern at or above 70 ppb, and about 26% are estimated to experience one or more exposures of concern at or above 60 ppb.

In addition to estimated exposures of concern, the Administrator also considers HREA estimates of the occurrence of O_3-induced lung function decrements. In doing so, she particularly notes CASAC advice that ''estimation of FEV_1 decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV_1 decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease'' (Frey, 2014c, p. 3). The Administrator notes that while single occurrences of O_3-induced lung function decrements could be adverse for some people, as discussed above (II.B.3), a more general consensus view of the potential adversity of such decrements emerges as the frequency of occurrences increases. Therefore, the Administrator focuses primarily on the estimates of two or more O_3-induced lung function decrements.

When averaged over the years evaluated in the HREA, the Administrator notes that the current standard is estimated to allow about 1 to 3% of children in the 15 urban study areas (corresponding to almost 400,000 children) to experience two or more O_3-induced lung function decrements ≥15%, and to allow about 8 to 12% of children (corresponding to about 180,000 asthmatic children [116]) to experience two or more O_3-induced lung function decrements ≥10%. Nationally, larger numbers of children would be expected to experience such O_3-induced decrements if the current standard were to be just met. The current standard is also estimated to allow about 3 to 5% of children in the urban study areas to experience one or more decrements ≥15% and about 14 to 19% of children to experience one or more decrements ≥10%. In the worst-case year and location, the current standard is estimated to allow 4% of children in the urban study areas to experience two or more decrements ≥15% (and 7% to experience one or more such decrements) and 14% of children to experience two or more decrements ≥10% (and 22% to experience one or more such decrements).

In further considering the HREA results, the Administrator considers the epidemiology-based risk estimates. As discussed above, compared to the weight given to HREA estimates of exposures of concern and lung function risks, she places relatively less weight on epidemiology-based risk estimates. In giving some consideration to these

[115] Almost no children in those areas would be estimated to experience two or more exposures of concern at or above 80 ppb.

[116] As noted above, CASAC concluded that ''an FEV1 decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease'' (Frey, 2014c, p. 3) and that such decrements ''could be adverse for people with lung disease'' (Frey, 2014c, p. 7).

risk estimates, the Administrator notes estimates of total risks (*i.e.,* based on the full distributions of ambient O_3 concentrations) and risks associated with O_3 concentrations in the upper portions of ambient distributions. The Administrator notes that estimates of total risks are based on the assumption that concentration-response relationships remain linear over the entire distributions of ambient O_3 concentrations. With regard to total risks, she notes that the HREA estimates thousands of O_3-associated hospital admissions, emergency department visits, and deaths per year for air quality conditions associated with just meeting the current standard in the 12 urban study areas (II.C.3).

However, the Administrator also notes the increasing uncertainty associated with the shapes of concentration-response curves for O_3 concentrations in the lower portions of ambient distributions. She particularly notes that there is less certainty in the shape of concentration-response functions for area-wide O_3 concentrations at the lower ends of warm season distributions (*i.e.,* below about 20 to 40 ppb depending on the O_3 metric, health endpoint, and study population) (U.S. EPA, 2013a, section 2.5.4.4). The Administrator further notes the evidence from controlled human exposure studies, which provide the strongest support for O_3-induced effects following exposures to O_3 concentrations corresponding to the upper portions of typical ambient distributions (*i.e.,* 60 ppb and above). Therefore, the Administrator judges it appropriate to focus on risks associated with O_3 concentrations in the upper portions of ambient distributions. Even when considering only area-wide O_3 concentrations from the upper portions of seasonal distributions, the Administrator notes that the current standard is estimated to allow hundreds to thousands of O_3-associated deaths per year in urban study areas (II.C.3).

Although the Administrator notes the HREA conclusions indicating somewhat less confidence in estimates of O_3-associated mortality and morbidity risks, compared to estimates of exposures of concern and risk of lung function decrements, she concludes that the general magnitude of mortality and morbidity risk estimates suggests the potential for a substantial number of O_3-associated deaths and adverse respiratory events to occur nationally, even when the current standard is met. She especially notes that this is the case based on the risks associated with the upper ends of distributions of ambient O_3 concentrations, where she has the greatest confidence in O_3-attributable effects.

In addition to the evidence and exposure/risk information discussed above, the Administrator also takes note of the CASAC advice in the current review and in the 2010 proposed reconsideration of the 2008 decision establishing the current standard. As discussed in more detail above, the current CASAC ''finds that the current NAAQS for ozone is not protective of human health'' and ''unanimously recommends that the Administrator revise the current primary ozone standard to protect public health'' (Frey, 2014c, p. 5). The prior CASAC O_3 Panel likewise recommended revision of the current standard to one with a lower level. This earlier recommendation was based entirely on the evidence and information in the record for the 2008 standard decision, which, as discussed above, has been substantially strengthened in the current review (Samet, 2011; Samet, 2012).

In consideration of all of the above, the Administrator proposes that the current primary O_3 standard is not adequate to protect public health, and that it should be revised to provide increased public health protection. This proposed decision is based on the Administrator's initial conclusions that the available evidence and exposure and risk information clearly call into question the adequacy of public health protection provided by the current primary standard and, therefore, that the current standard is not requisite to protect public health with an adequate margin of safety. With regard to the evidence, she specifically notes that (1) controlled human exposure studies provide support for the occurrence of adverse respiratory effects following exposures to O_3 concentrations below the level of the current standard (*i.e.,* as low as 72 ppb), and that (2) single-city epidemiologic studies provide support for the occurrence of adverse respiratory effects under air quality conditions that would likely meet the current standard, with multicity studies providing some support for this conclusion for a broader range of effects (*i.e.,* including mortality). Courts have repeatedly held that this type of evidence justifies an Administrator's conclusion that it is ''appropriate'' (within the meaning of section 109 (d)(1) of the CAA) to revise a primary NAAQS to provide further protection of public health.[117] In addition, based on the analyses in the HREA, the Administrator initially concludes that the exposures and risks projected to remain upon meeting the current standard can reasonably be judged to be important from a public health perspective. Thus, she reaches the proposed conclusion that the evidence and information, together with CASAC advice based on their consideration of that evidence and information, provide strong support for revising the current primary standard in order to increase public health protection against an array of adverse effects that range from decreased lung function and respiratory symptoms to more serious indicators of morbidity (*e.g.,* including emergency department visits and hospital admissions), and mortality.

The Administrator solicits comment on her proposed decision to revise the current primary O_3 NAAQS, including on her considerations and proposed conclusions based on the scientific evidence, exposure/risk information, and CASAC advice. In doing so, she recognizes that some have expressed alternative approaches to viewing the evidence and information, including alternative approaches to viewing, evaluating, and weighing important uncertainties. In some cases, these alternative approaches have led some public commenters to recommend retaining the current standard. Given these alternative views, in addition to proposing to revise the current primary O_3 standard, the Administrator solicits comment on the option of retaining that standard. In doing so, she also solicits comment on the potential approaches to viewing the scientific evidence and exposure/risk information that could support a conclusion that the current standard is requisite to protect public health with an adequate margin of safety.

E. Conclusions on the Elements of the Primary Standard

Having reached the proposed conclusion that the currently available scientific evidence and exposure/risk information call into question the adequacy of the current O_3 standard, the Administrator next considers the range of alternative standards supported by that evidence and information. Consistent with her consideration of the adequacy of the current standard, the Administrator's proposed conclusions on alternative standards are informed by the available scientific evidence assessed in the ISA, exposure/risk information presented and assessed in the HREA, the evidence-based and exposure-/risk-based considerations and conclusions in the PA, CASAC advice, and input from members of the public. The sections below discuss the evidence

[117] See *e.g. State of Mississippi,* 744 F. 3d at 1345; *American Farm Bureau,* 559 F. 3d at 525–26.

and exposure/risk information, CASAC advice and public input, and the Administrator's proposed conclusions, for the major elements of the NAAQS: indicator (II.E.1), averaging time (II.E.2), form (II.E.3), and level (II.E.4).

1. Indicator

In the last review, the EPA focused on O_3 as the most appropriate indicator for a standard meant to provide protection against ambient photochemical oxidants. In this review, while the complex atmospheric chemistry in which O_3 plays a key role has been highlighted, no alternatives to O_3 have been advanced as being a more appropriate indicator for ambient photochemical oxidants. More specifically, the ISA noted that O_3 is the only photochemical oxidant (other than NO_2) that is routinely monitored and for which a comprehensive database exists (U.S. EPA, 2013a, section 3.6). Data for other photochemical oxidants (*e.g.,* PAN, H_2O_2, etc.) typically have been obtained only as part of special field studies. Consequently, no data on nationwide patterns of occurrence are available for these other oxidants; nor are extensive data available on the relationships of concentrations and patterns of these oxidants to those of O_3 (U.S. EPA, 2013a, section 3.6). In its review of the second draft PA, CASAC stated ''The indicator of ozone is appropriate based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants'' (Frey, 2014c, p. ii).

In addition, the PA notes that meeting an O_3 standard can be expected to provide some degree of protection against potential health effects that may be independently associated with other photochemical oxidants, even though such effects are not discernible from currently available studies indexed by O_3 alone (U.S. EPA, 2014c, section 4.1). That is, since the precursor emissions that lead to the formation of O_3 generally also lead to the formation of other photochemical oxidants, measures leading to reductions in population exposures to O_3 can generally be expected to lead to reductions in population exposures to other photochemical oxidants. In considering this information, and CASAC's advice, the Administrator reaches the proposed conclusion that O_3 remains the most appropriate indicator for a standard meant to provide protection against photochemical oxidants.[118]

2. Averaging Time

The EPA established the current 8-hour averaging time[119] for the primary O_3 NAAQS in 1997 (62 FR 38856). The decision on averaging time in that review was based on numerous controlled human exposure and epidemiologic studies reporting associations between 6 to 8 hour O_3 concentrations and adverse respiratory effects (62 FR 38861). It was also noted that a standard with a max 8-hour averaging time is likely to provide substantial protection against respiratory effects associated with 1-hour peak O_3 concentrations. Similar conclusions were reached in the last O_3 NAAQS review and thus, the 8-hour averaging time was retained in 2008.

In reaching a proposed conclusion on averaging time in the current review, the Administrator considers the extent to which the available evidence continues to support the appropriateness of a standard with an 8-hour averaging time. Specifically, the Administrator considers the extent to which the available information indicates that a standard with the current 8-hour averaging time provides appropriate protection against short- and long-term O_3 exposures.

a. Short-Term

As an initial consideration with respect to the most appropriate averaging time for the O_3 NAAQS, the Administrator notes that the strongest evidence for O_3-associated health effects is for respiratory effects following short-term exposures. More specifically, the Administrator notes the ISA conclusion that the evidence is ''sufficient to infer a causal relationship'' between short-term O_3 exposures and respiratory effects. The ISA also judges that for short-term O_3 exposures, the evidence indicates ''likely to be causal'' relationships with both cardiovascular effects and mortality (U.S. EPA, 2013a, section 2.5.2). Therefore, as in past reviews, the strength of the available scientific evidence provides strong support for a standard that protects the public health against short-term exposures to O_3.

In first considering the level of support available for specific short-term averaging times, the Administrator notes the evidence available from controlled human exposure studies. As discussed in more detail in chapter 3 of the PA, substantial health effects evidence from controlled human exposure studies demonstrates that a wide range of respiratory effects (*e.g.,* pulmonary function decrements, increases in respiratory symptoms, lung inflammation, lung permeability, decreased lung host defense, and AHR) occur in healthy adults following 6.6 hour exposures to O_3 (U.S. EPA, 2013a, section 6.2.1.1). Compared to studies evaluating shorter exposure durations (*e.g.,* 1-hour), studies evaluating 6.6 hour exposures in healthy adults have reported respiratory effects at lower O_3 exposure concentrations and at more moderate levels of exertion.

The Administrator also notes the strength of evidence from epidemiologic studies that have evaluated a wide variety of populations (*e.g.,* including at-risk lifestages and populations, such as children and people with asthma, respectively). A number of different averaging times are used in O_3 epidemiologic studies, with the most common being the max 1-hour concentration within a 24-hour period (1-hour max), the max 8-hour average concentration within a 24-hour period (8-hr max), and the 24-hour average. These studies are summarized above and assessed in detail in chapter 6 of the ISA (U.S. EPA, 2013a). Limited evidence from time-series and panel epidemiologic studies comparing risk estimates across averaging times does not indicate that one exposure metric is more consistently or strongly associated with respiratory health effects or mortality, though the ISA notes some evidence for ''smaller O_3 risk estimates when using a 24-hour average exposure metric'' (U.S. EPA, 2013a, section 2.5.4.2; p. 2–31). For single- and multi-day average O_3 concentrations, lung function decrements were associated with 1-hour max, 8-hour max, and 24-hour average ambient O_3 concentrations, with no strong difference in the consistency or magnitude of association among the averaging times (U.S. EPA, 2013a, p. 6–71). Similarly, in studies of short-term exposure to O_3 and mortality, Smith et al. (2009) and Darrow et al. (2011) have reported high correlations between risk estimates calculated using 24-hour average, 8-hour max, and 1-hour max averaging times (U.S. EPA, 2013a, p. 6–253). Thus, the Administrator notes that the epidemiologic evidence alone does not provide a strong basis for distinguishing between the appropriateness of 1-hour, 8-hour, and 24-hour averaging times.

Considering the health information discussed above, the Administrator concludes that an 8-hour averaging time remains appropriate for addressing health effects associated with short-term exposures to ambient O_3. An 8-hour

[118] The DC Circuit upheld the use of O_3 as the indicator for photochemical oxidants based on these same considerations. *American Petroleum Inst.* v. *Costle,* 665 F. 2d 1176, 1186 (D.C. Cir. 1981).

[119] This 8-hour averaging time reflects daily max 8-hour average O_3 concentrations.

averaging time is similar to the exposure periods evaluated in controlled human exposure studies, including recent studies that provide evidence for respiratory effects following exposures to O_3 concentrations below the level of the current standard. In addition, epidemiologic studies provide evidence for health effect associations with 8-hour O_3 concentrations, as well as with 1-hour and 24-hour concentrations. As in previous reviews, the Administrator notes that a standard with an 8-hour averaging time (combined with an appropriate standard form and level) would also be expected to provide substantial protection against health effects attributable to 1-hour and 24-hour exposures (*e.g.,* 62 FR 38861, July 18, 1997). This conclusion is consistent with the advice received from CASAC that ''the current 8-hour averaging time is justified by the combined evidence from epidemiologic and clinical studies'' (Frey, 2014c, p. 6).

b. Long-Term

The ISA concludes that the evidence for long-term O_3 exposures indicates that there is ''likely to be a causal relationship'' with respiratory effects (U.S. EPA, 2013a, chapter 7). Thus, in this review the Administrator also considers the extent to which currently available evidence and exposure/risk information suggests that a standard with an 8-hour averaging time can provide protection against respiratory effects associated with longer term exposures to ambient O_3.

In considering this issue in the last review of the O_3 NAAQS, the Staff Paper noted that ''because long-term air quality patterns would be improved in areas coming into attainment with an 8-hr standard, the potential risk of health effects associated with long-term exposures would be reduced in any area meeting an 8-hr standard'' (U.S. EPA, 2007, p. 6–57). In the current review, the PA further evaluates this issue, with a focus on the long-term O_3 metrics reported to be associated with mortality or morbidity in recent epidemiologic studies. As discussed in section 3.1.3 of the PA (U.S. EPA, 2014c, section 4.2), much of the recent evidence for such associations is based on studies that defined long-term O_3 in terms of seasonal averages of daily maximum 1-hour or 8-hour concentrations.

As an initial consideration, the Administrator notes the risk results from the HREA for respiratory mortality associated with long-term O_3 concentrations. These HREA analyses indicate that as air quality is adjusted to just meet the current 8-hour standard, most urban study areas are estimated to experience reductions in respiratory mortality associated with long-term O_3 concentrations based on the seasonal averages of 1-hour daily maximum O_3 concentrations evaluated in the study by Jerrett et al. (2009) (U.S. EPA, 2014a, chapter 7).[120] As air quality is adjusted to meet lower alternative standard levels, for standards based on 3-year averages of the annual fourth-highest daily maximum 8-hour O_3 concentrations, respiratory mortality risks are estimated to be reduced further in urban study areas. This analysis indicates that an O_3 standard with an 8-hour averaging time, when coupled with an appropriate form and level, can reduce respiratory mortality reported to be associated with long-term O_3 concentrations.

In further considering the study by Jerrett et al. (2009), the Administrator notes the PA comparison of long-term O_3 concentrations following model adjustment in urban study areas (*i.e.,* adjusted to meet the current and alternative 8-hour standards) to the concentrations present in study cities that provided the basis for the positive and statistically significant association with respiratory mortality. As indicated in Table 4–3 of the PA (U.S. EPA, 2014c, section 4.2), this comparison suggests that a standard with an 8-hour averaging time can decrease seasonal averages of 1-hour daily maximum O_3 concentrations, and can maintain those O_3 concentrations below the seasonal average concentration where the study indicates the most confidence in the reported concentration-response relationship with respiratory mortality (U.S. EPA, 2014c, sections 4.2 and 4.4.1).

The Administrator also notes that the HREA conducted analyses evaluating the impacts of reducing regional NO_X emissions on the seasonal averages of daily maximum 8-hour O_3 concentrations. Seasonal averages of 8-hour daily max O_3 concentrations reflect long-term metrics that have been reported to be associated with respiratory morbidity effects in several recent O_3 epidemiologic studies (*e.g.,* Islam et al., 2008; Lin et al., 2008; Salam et al., 2009). The HREA analyses indicate that the large majority of the U.S. population lives in locations where reducing NO_X emissions would be expected to result in decreases in seasonal averages of daily max 8-hour ambient O_3 concentrations (U.S. EPA, 2014a, chapter 8). Thus, consistent with the respiratory mortality risk estimates noted above, these analyses suggest that reductions in O_3 precursor emissions in order to meet a standard with an 8-hour averaging time would also be expected to reduce the long-term O_3 concentrations that have been reported in recent epidemiologic studies to be associated with respiratory morbidity.

c. Administrator's Proposed Conclusion on Averaging Time

Taken together, the Administrator notes that the analyses summarized above indicate that a standard with an 8-hour averaging time, coupled with the current 4th high form and an appropriate level, would be expected to provide appropriate protection against the short- and long-term O_3 concentrations that have been reported to be associated with respiratory morbidity and mortality. The CASAC agreed with this conclusion, stating that ''[t]he current 8-hour averaging time is justified by the combined evidence from epidemiologic and clinical studies'' and that ''[t]he 8-hour averaging window also provides protection against the adverse impacts of long-term ozone exposures, which were found to be ''likely causal'' for respiratory effects and premature mortality'' (Frey, 2014c, p. 6). Therefore, considering the available evidence and exposure risk information, and CASAC's advice, the Administrator proposes to retain the current 8-hour averaging time, and not to set an additional standard with a different averaging time.

3. Form

The ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains that standard. The foremost consideration in selecting a form is the adequacy of the public health protection provided by the combination of the form and the other elements of the standard. In this review, the Administrator considers the extent to which the available evidence and/or information continue to support the appropriateness of a standard with the current form, defined by the 3-year average of annual 4th-highest 8-hour daily maximum O_3 concentrations.

The EPA established the current form of the primary O_3 NAAQS in 1997 (62 FR 38856). Prior to that time, the standard had a ''1-expected-exceedance'' form.[121] An advantage of the current concentration-based form recognized in the 1997 review is that

[120] Though the Administrator also notes important uncertainties associated with these risk estimates, as discussed above (II.C.3.b).

[121] For a standard with a 1-expected-exceedance form to be met at an air quality monitoring site, the fourth-highest air quality value in 3 years, given adjustments for missing data, must be less than or equal to the level of the standard.

such a form better reflects the continuum of health effects associated with increasing ambient O_3 concentrations. Unlike an expected exceedance form, a concentration-based form gives proportionally more weight to years when 8-hour O_3 concentrations are well above the level of the standard than years when 8-hour O_3 concentrations are just above the level of the standard.[122] It was judged appropriate to give more weight to higher O_3 concentrations, given that available health evidence indicated a continuum of effects associated with exposures to varying concentrations of O_3, and given that the extent to which public health is affected by exposure to ambient O_3 is related to the actual magnitude of the O_3 concentration, not just whether the concentration is above a specified level.

During the 1997 review, the EPA considered a range of alternative ''concentration-based'' forms, including the second-, third-, fourth- and fifth-highest daily maximum 8-hour concentrations in an O_3 season. The fourth-highest daily maximum was selected, recognizing that a less restrictive form (*e.g.,* fifth highest) would allow a larger percentage of sites to experience O_3 peaks above the level of the standard, and would allow more days on which the level of the standard may be exceeded when the site attains the standard (62 FR 38856). Consideration was also given to setting a standard with a form that would provide a margin of safety against possible but uncertain chronic effects, and would provide greater stability to ongoing control programs.[123] A more restrictive form was not selected, recognizing that the differences in the degree of protection afforded by the alternatives were not well enough understood to use any such differences as a basis for choosing the most restrictive forms (62 FR 38856).

In the 2008 review, the EPA additionally considered the potential value of a percentile-based form. In doing so, the EPA recognized that such a statistic is useful for comparing datasets of varying length because it samples approximately the same place in the distribution of air quality values, whether the dataset is several months or several years long. However, the EPA concluded that a percentile-based statistic would not be effective in ensuring the same degree of public health protection across the country. Specifically, a percentile-based form would allow more days with higher air quality values in locations with longer O_3 seasons relative to places with shorter O_3 seasons. Thus, in the 2008 review, the EPA concluded that a form based on the nth-highest maximum O_3 concentration would more effectively ensure that people who live in areas with different length O_3 seasons receive the same degree of public health protection.

Based on analyses of forms specified in terms of an nth-highest concentration (n ranged from 3 to 5), advice from CASAC, and public comment,[124] the Administrator concluded that a 4th-highest daily maximum should be retained (73 FR 16465, March 27, 2008). In reaching this decision, the Administrator recognized that ''there is not a clear health-based threshold for selecting a particular nth-highest daily maximum form of the standard'' and that ''the adequacy of the public health protection provided by the combination of the level and form is a foremost consideration'' (73 FR 16475, March 27, 2008). Based on this, the Administrator judged that the existing form (4th-highest daily maximum 8-hour average concentration) should be retained, recognizing the increase in public health protection provided by combining this form with a lower standard level (*i.e.,* 75 ppb).

The Administrator also recognized that it is important to have a form that provides stability with regard to implementation of the standard. In the case of O_3, for example, he noted the importance of a form insulated from the impacts of the meteorological events that are conducive to O_3 formation. Such events could have the effect of reducing public health protection, to the extent they result in frequent shifts in and out of attainment due to meteorological conditions. The Administrator noted that such frequent shifting could disrupt an area's ongoing implementation plans and associated control programs (73 FR 16474, March 27, 2008). In his final decision, the Administrator judged that a 4th high form ''provides a stable target for implementing programs to improve air quality'' (73 FR 16475, March 27, 2008).

In the current review, the Administrator considers the extent to which newly available information provides support for the current form. In so doing, she takes note of the conclusions of prior reviews summarized above. She recognizes the value of an nth-high statistic over that of an expected exceedance or percentile-based form in the case of the O_3 standard, for the reasons summarized above. The Administrator additionally takes note of the importance of stability in implementation to achieving the level of protection specified by the NAAQS. Specifically, she notes that to the extent areas engaged in implementing the O_3 NAAQS frequently shift from meeting the standard to violating the standard, it is possible that ongoing implementation plans and associated control programs could be disrupted, thereby reducing public health protection.

In light of this, while giving foremost consideration to the adequacy of public health protection provided by the combination of all elements of the standard, including the form, the Administrator considers particularly findings from prior reviews with regard to the use of the nth-high metric. As noted above, the 4th-highest daily maximum was selected in recognition of the public health protection provided by this form, when coupled with an appropriate averaging time and level, and recognizing that such a form can provide stability for implementation programs. The Administrator concludes that the currently available evidence and information do not call into question these conclusions from previous reviews. In reaching this conclusion, the Administrator notes that CASAC concurred that the O_3 standard should be based on the fourth highest, daily maximum 8-hour average value (averaged over 3 years), stating that this form ''provides health protection while allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations which, in turn, provides programmatic stability'' (Frey, 2014c, p. 6). Thus, a standard with the current 4th high form, coupled with a level lower than 75 ppb

[122] As discussed (61 FR 65731), this is because with an exceedance-based form, days on which the ambient O_3 concentration is well above the level of the standard are given equal weight to those days on which the O_3 concentration is just above the standard (*i.e.,* each day is counted as one exceedance), even though the public health impact of such days would be very different. With a concentration-based form, days on which higher O_3 concentrations occur would weigh proportionally more than days with lower O_3 concentrations since the actual concentrations are used directly to calculate whether the standard is met or violated.

[123] See *American Trucking Assn's* v. *EPA,* 283 F. 3d at 374–75 (less stable implementation programs may be less effective, and therefore the EPA can consider programmatic stability in determining the form of a NAAQS).

[124] In the 2008 review, one group of commenters expressed the view that the standard was not adequate and supported a more health-protective form (*e.g.,* a second- or third-highest daily max form). Another group of commenters expressed the view that the standard was adequate and did not provide any views on alternative forms that would be appropriate should the Administrator consider revisions to the standard. The Administrator considered the protection afforded by the combination of level and form in revising the standard in 2008 to 75 ppb, as a 3-year average of the annual fourth-highest daily max 8-hour concentrations (73 FR 16475, March 27, 2008).

as discussed below, would be expected to increase public health protection relative to the current standard while continuing to provide stability for implementation programs. Therefore, the Administrator proposes to retain the current 4th-highest daily maximum form for an O_3 standard with an 8-hour averaging time and a revised level, as discussed below.

4. Level

The Administrator next considers the extent to which alternative levels below 75 ppb could provide greater protection than the current primary standard against short- and long- term exposures to O_3 in ambient air, for a standard based on the 3-year average of the annual 4th highest daily maximum 8-hour O_3 concentration. In doing so, she particularly notes the evidence-based and exposure-/risk-based considerations in the PA, which take into account the experimental and epidemiologic evidence as assessed in the ISA; quantitative estimates of O_3 exposures and health risks in at-risk populations provided by the HREA; uncertainties and limitations associated with this evidence and information; CASAC advice; and public input (U.S. EPA, 2014c, sections 4.4 and 4.5). Section II.E.4.a below summarizes the PA's approach to considering the scientific evidence and the exposure/risk information related to level of the primary standard. Section II.E.4.b presents the PA's conclusions on alternative primary O_3 standard levels. Section II.E.4.c summarizes CASAC advice on the level of the primary standard, and public input received thus far. Section II.E.4.d presents the Administrator's proposed conclusions on primary O_3 standard levels.

a. PA Approach to Considering the Evidence and Information Related to Alternative Levels of the Primary Standard

The PA's approach to reaching conclusions on alternative standard levels focuses on the evidence from controlled human exposure and epidemiologic studies, as assessed in the ISA (U.S. EPA, 2013a), and the exposure and health risk analyses presented in the HREA (U.S. EPA, 2014a). This approach is discussed in detail in Chapters 1 and 4 of the PA (U.S. EPA, 2014c, sections 1.3, 4.6), and is summarized below.

As an initial matter, the PA notes that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following exposures to specific O_3 concentrations. Consistent with this, CASAC concluded that ''the scientific evidence supporting the finding that the current standard is inadequate to protect public health is strongest based on the controlled human exposure studies of respiratory effects'' (Frey, 2014c, p. 5). As discussed above and in section 3.1.2.1 of the PA (U.S. EPA, 2014c), controlled human exposure studies have reported a variety of respiratory effects in healthy adults following exposures to O_3 concentrations of 60, 72,[125] or 80 ppb, and higher.

Given the evidence for respiratory effects from controlled human exposure studies, the PA considers the extent to which standards with revised levels would be estimated to protect at-risk populations against exposures of concern to O_3 concentrations at or above the health benchmark concentrations of 60, 70, and 80 ppb (*i.e.,* based on HREA estimates of one or more and two or more exposures of concern). In doing so, the PA notes the CASAC conclusion that (Frey, 2014c, p. 6):

> The 80 ppb-8hr benchmark level represents an exposure level for which there is substantial clinical evidence demonstrating a range of ozone-related effects including lung inflammation and airway responsiveness in healthy individuals. The 70 ppb-8hr benchmark level reflects the fact that in healthy subjects, decreases in lung function and respiratory symptoms occur at concentrations as low as 72 ppb and that these effects almost certainly occur in some people, including asthmatics and others with low lung function who are less tolerant of such effects, at levels of 70 ppb and below. The 60 ppb-8hr benchmark level represents the lowest exposure level at which ozone-related effects have been observed in clinical studies of healthy individuals.

The PA also notes that, due to individual variability in responsiveness, only a subset of people who experience exposures at or above the three benchmark concentrations can be expected to experience associated health effects, and that available data are not sufficient to quantify that subset of people for most of the endpoints that have been evaluated in controlled human exposure studies (*i.e.,* with the exception of FEV_1 decrements). The PA views the health effects evidence as a continuum with greater confidence and less uncertainty about the occurrence of adverse health effects at higher O_3 exposure concentrations, and less confidence and greater uncertainty as one considers lower exposure concentrations (U.S. EPA, 2014c, section 3.2.2, p. 3–101).

While there is greater uncertainty regarding the occurrence of adverse health effects at lower concentrations, the PA also notes that the controlled human exposure studies that provided the basis for benchmark concentrations have not evaluated responses in populations at the greatest risk from exposures to O_3 (*e.g.,* children, people with asthma). Compared to the healthy people included in most controlled human exposure studies, members of at-risk populations and lifestages are at greater risk of experiencing adverse effects. Thus, the effects reported in healthy adults at each of the benchmark concentrations may underestimate effects in these at-risk groups. In considering the health evidence within the context of drawing conclusions on alternative standard levels, the PA balances concerns about the potential for adverse health effects, especially in at-risk populations, with the increasing uncertainty regarding the likelihood of such effects following exposures to lower O_3 concentrations.

With respect to the lung function decrements that have been evaluated in controlled human exposure studies, the PA considers the extent to which standards with revised levels would be estimated to protect healthy and at-risk populations against O_3-induced lung function decrements large enough to be adverse in some people (based on quantitative risk estimates in the HREA). As discussed in section 3.1.3 of the PA (U.S. EPA, 2014c) and section II.B.3 above, although some experts would judge single occurrences of moderate responses to be a nuisance, especially for healthy individuals, a more general consensus view of the adversity of moderate lung function decrements emerges as the frequency of occurrence increases. Repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered to be adverse, since they could well set the stage for more serious illness (73 FR 16448). In reaching conclusions on alternative standard levels, the PA considers the extent to which standards with revised levels would be estimated to protect healthy and at-risk populations against one or more, and two or more, moderate (*i.e.,* FEV_1 decrements ≥10% and ≥15%) and large (*i.e.,* FEV_1 decrements ≥20%) lung function decrements.

In evaluating the epidemiologic evidence within the context of drawing conclusions on alternative standard levels, the PA considers the extent to which available studies have reported associations with emergency

[125] As noted above, for the 70 ppb exposure concentration Schelegle et al. (2009) reported that the actual 6.6-hour mean exposure concentration was 72 ppb.

department visits, hospital admissions, and/or mortality in locations that would likely have met alternative standards with levels below 75 ppb. In evaluating the epidemiologic evidence in this way, the PA considers both multicity and single-city studies, recognizing the strengths and limitations of each. In particular, while single-city studies are more limited than multicity studies in terms of statistical power and geographic coverage, conclusions linking air quality in a specific area with health effect associations in that same area can be made with greater certainty for single-city studies (*i.e.,* compared to multicity studies reporting only multicity effect estimates).

The PA also considers the epidemiologic evidence within the context of epidemiology-based risk estimates. Compared to the weight given to HREA estimates of exposures of concern and lung function risks, and the weight given to the evidence, the PA places relatively less weight on epidemiologic-based risk estimates. In doing so, the PA notes that the overall conclusions from the HREA likewise reflect less confidence in estimates of epidemiologic-based risks than in estimates of exposures and lung function risks. The determination to attach less weight to the epidemiologic-based estimates reflects the uncertainties associated with mortality and morbidity risk estimates, including the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions at lower O_3 concentrations (U.S. EPA, 2014a, section 9.6). The HREA also concludes that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study (even though that study is well-designed) and because of the uncertainty in that study about the existence and level of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6).

In considering the epidemiology-based risk estimates, the PA focuses on the extent to which potential alternative O_3 standards with levels below 75 ppb are estimated to reduce the risk of O_3-associated mortality.[126] As discussed for the current standard (II.D.2.c), the PA considers estimates of total risk (*i.e.,* based on the full distributions of ambient O_3 concentrations) and estimates of risk associated with O_3 concentrations in the upper portions of ambient distributions.

b. PA Conclusions on Alternative O_3 Standard Levels

Using the approach discussed above to consider the scientific evidence and exposure/risk information, CASAC advice (II.E.4.c, below), and public comments, the PA reaches the conclusion that it is appropriate for the Administrator to consider alternative primary O_3 standard levels from 70 to 60 ppb. The basis for this conclusion is discussed in detail in sections 4.4.1 and 4.4.2 of the PA (U.S. EPA, 2014c), and is summarized below.

With regard to controlled human exposure studies, the PA considers the lowest O_3 exposure concentrations at which various effects have been evaluated and statistically significant effects reported. The PA also considers the potential for reported effects to be adverse, including in at-risk populations and lifestages. As discussed in section 3.1.2.1 of the PA (U.S. EPA, 2014c), controlled human exposure studies provide evidence of respiratory symptoms combined with lung function decrements (an adverse response based on ATS criteria) in healthy adults following 6.6 hour exposures to O_3 concentrations as low as 72 ppb, and evidence of potentially adverse lung function decrements and airway inflammation following 6.6 hour exposures to O_3 concentrations as low as 60 ppb.

Although some studies show that respiratory symptoms also develop during exposures to 60 ppb O_3, the increase in symptoms has not been reported to reach statistical significance by the end of the 6.6 hour exposure period (Adams, 2006; Schelegle et al., 2009). Thus, while significant increases in respiratory symptoms combined with lung function decrements have not been reported following exposures to 60 ppb O_3, this combination of effects is likely to occur to some degree in healthy adults with 6.6-hour exposures to concentrations below 72 ppb, and also are more likely to occur with longer (*i.e.,* 8-hour) exposures.[127] In addition, pulmonary inflammation, particularly if experienced repeatedly, provides a mechanism by which O_3 may cause other more serious respiratory morbidity effects (*e.g.,* asthma exacerbations) and possibly extrapulmonary effects. As discussed in section 3.1.2.1 of the PA (U.S. EPA, 2014c), the physiological effects reported in controlled human exposure studies down to 60 ppb O_3 have been linked to aggravation of asthma and increased susceptibility to respiratory infection, potentially leading to increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions.

With regard to the lowest exposure concentration shown to cause respiratory effects (*i.e.,* 60 ppb),[128] the PA notes that most controlled human exposure studies have not evaluated O_3 concentrations below 60 ppb. Therefore, 60 ppb does not necessarily reflect an exposure concentration below which effects such as lung function decrements and airway inflammation no longer occur. This is particularly the case given that controlled human exposure studies were conducted in healthy adults, while people with asthma, including asthmatic children, are likely to be more sensitive to O_3-induced respiratory effects.

With regard to other O_3-induced effects, the PA notes that AHR and impaired lung host defense capabilities have been reported in healthy adults engaged in moderate exertion following exposures to O_3 concentrations as low as 80 ppb, the lowest concentration evaluated for these effects. As discussed in section 3.1.2.1 of the PA (U.S. EPA, 2014c), these physiological effects have been linked to aggravation of asthma and increased susceptibility to respiratory infection, potentially leading to increased medication use, increased school and work absences, increased visits to doctors' offices and emergency departments, and increased hospital admissions. These are all indicators of adverse O_3-related morbidity effects, which are consistent with, and provide plausibility for, the adverse morbidity effects and mortality effects observed in epidemiologic studies.

Based on consideration of the above evidence, the PA concludes that available controlled human exposure studies support considering alternative O_3 standard levels from 70 to 60 ppb in

[126] Differences in estimated respiratory morbidity risks between alternative standard levels are similar to the differences estimated for total mortality associated with short-term O_3 concentrations.

[127] In addition, CASAC observed that, ''adverse health effects in young healthy adults occur with exposures to 72 ppb of ozone for 6.6 hours'' and that ''[i]t is the judgment of CASAC that if subjects had been exposed to ozone using the 8-hour averaging period used in the standard, adverse effects could have occurred at [a] lower concentration. Further, in our judgment, the level at which adverse effects might be observed would likely be lower for more sensitive subgroups, such as those with asthma'' (Frey, 2014c, p. 5).

[128] As discussed above (II.B.2), prolonged 6.6 exposure to 40 ppb O_3 has been shown to result in a small decrease in group mean FEV_1 that is not statistically different from responses following exposure to filtered air (Adams, 2002; Adams, 2006).

the current review. In reaching this conclusion, the PA notes that 70 ppb is just below the O_3 exposure concentration reported to result in lung function decrements and respiratory symptoms in healthy adults (*i.e.,* 72 ppb), a combination of effects that meet ATS criteria for an adverse response. In addition, while 70 ppb is well below the 80 ppb exposure concentration shown to cause potentially adverse respiratory effects such as AHR and impaired host-defense capabilities, these effects have not been evaluated at exposure concentrations below 80 ppb and there is no reason to believe that 80 ppb represents a threshold for such effects. In addition, potentially adverse lung function decrements and pulmonary inflammation have been demonstrated to occur in healthy adults at 60 ppb. Thus, 60 ppb is a short-term exposure concentration that may be reasonably concluded to elicit adverse effects in at-risk groups.

The PA further notes that the range of alternative levels from 70 to 60 ppb is supported by evidence from epidemiologic studies and by exposure and risk estimates from the HREA. This evidence and exposure/risk information indicate that a level from anywhere in the range of 70 to 60 ppb would be expected to result in important public health improvements over the current standard. In particular, compared to the current standard a revised standard with a level from 70 to 60 ppb would be expected to (1) more effectively maintain short- and long-term O_3 concentrations below those present in the epidemiologic studies that reported significant O_3 health effect associations in locations likely to have met the current standard; (2) reduce the occurrence of exposures of concern to O_3 concentrations that result in respiratory effects in healthy adults (at or above 60, 70, and 80 ppb); (3) reduce the occurrence of moderate-to-large O_3-induced lung function decrements; and (4) reduce the risk of O_3-associated mortality and morbidity, particularly the risk associated with the upper portions of the distributions of ambient O_3 concentrations. The PA also notes that the range of levels from 70 to 60 ppb corresponds to the range of levels recommended for consideration by CASAC, based on the available evidence and information (Frey, 2014a; Frey, 2014c).

In reaching a conclusion on whether it is appropriate to consider alternative standard levels below 60 ppb, the PA notes the following:

(1) While controlled human exposure studies provide evidence for O_3-induced respiratory effects following exposures to O_3 concentrations as low as 60 ppb, they do not provide evidence for adverse effects following exposures to lower concentrations. On this issue, CASAC concurred that 60 ppb O_3 is an appropriate and justifiable scientifically based lower bound for a revised primary standard, based upon findings of ''adverse effects, including clinically significant lung function decrements and airway inflammation, after exposures to 60 ppb ozone in healthy adults with moderate exertion (Adams, 2006; Schelegle et al., 2009; Brown et al., 2008; Kim et al., 2011), with limited evidence of adverse effects below 60 ppb'' (Frey, 2014c, p. 7).

(2) Based on the HREA results, meeting an O_3 standard with a level of 60 ppb would be expected to almost eliminate exposures of concern to O_3 concentrations at or above 60 ppb. To the extent lower exposure concentrations may result in adverse health effects in some people, a standard level of 60 ppb would be expected to also reduce exposures to O_3 concentrations below 60 ppb.

(3) U.S. and Canadian epidemiologic studies have not reported O_3 health effect associations based primarily on study locations likely to have met a standard with a level of 60 ppb.

(4) In all of the urban study areas evaluated, a standard with a level of 60 ppb would be expected to maintain long-term O_3 concentrations below those where a key study indicates the most confidence in a linear concentration-response relationship with respiratory mortality.

Given all of the above considerations the PA concludes that, compared to standards with levels from 70 to 60 ppb, the extent to which standards with levels below 60 ppb could result in further public health improvements becomes notably less certain. Therefore, the PA concludes that it is not appropriate in this review to consider standard levels below 60 ppb.

The following sections summarize the PA's consideration of the scientific evidence and exposure/risk information specifically related to potential alternative O_3 standards with levels from the upper (70 ppb) (II.E.4.c.i), middle (65 ppb) (II.E.4.c.ii), and lower (60 ppb) (II.E.4.c.iii) portions of the range of 70 to 60 ppb. Key exposure/risk information considered in the PA is summarized in Tables 4 and 5, below (from U.S. EPA, 2014c, Tables 4–4 and 4–5).

TABLE 4—SUMMARY OF ESTIMATED EXPOSURES OF CONCERN FOR POTENTIAL ALTERNATIVE O_3 STANDARD LEVELS OF 70, 65, 60 PPB IN URBAN CASE STUDY AREAS [129]

Benchmark level	Alternative standard level (ppb)	Average % children exposed [130]	Number of children (5 to 18 years) [number of asthmatic children] [131] [132]	Average % reduction from current standard [133]	% Children—worst year and worst area
One or more exposures of concern per season					
≥70 ppb	70	0.1–1.2	94,000 [10,000]	73	3.2
	65	0–0.2	14,000 [2,000]	95	0.5
	60	[134] 0	1,400 [200] [135]	100	0.1
≥60 ppb	70	3.3–10.2	1,176,000 [126,000]	46	18.9
	65	0–4.2	392,000 [42,000]	80	9.5

[129] All alternative standard levels evaluated in the HREA were effective at limiting exposures of concern at or above 80 ppb (U.S. EPA, 2014c, Figures 4–1 to 4–4). Therefore, Table 4 focuses on exposures of concern at or above the 70 and 60 ppb benchmark concentrations.

[130] Estimates for each urban case study area were averaged for the years evaluated in the HREA (2006 to 2010). Ranges reflect the ranges across urban study areas.

[131] Numbers of children exposed in each urban case study area were averaged over the years 2006 to 2010. These averages were then summed across urban study areas. Numbers are rounded to nearest thousand unless otherwise indicated.

[132] As noted in section II.C.3.a.ii, the responsiveness of asthmatics to O_3 exposures could depend on factors that have not been well-evaluated such as asthma severity, the effectiveness of asthma control, or the prevalence of medication use.

[133] Percent reductions in each urban study area were calculated and averaged across areas.

[134] Estimates smaller than 0.05% were rounded to zero.

[135] As discussed in section 4.3.3 of the HREA (U.S. EPA, 2014a), the model-based air quality adjustment approach used to estimate risks associated with the current and alternative standards was unable to estimate the distribution of ambient O_3 concentrations in New York City upon just meeting an alternative standard with a level of 60 ppb. Therefore, for the 60 ppb standard level the numbers of children and asthmatic children reflect all of the urban study areas except New York.

TABLE 4—SUMMARY OF ESTIMATED EXPOSURES OF CONCERN FOR POTENTIAL ALTERNATIVE O_3 STANDARD LEVELS OF 70, 65, 60 PPB IN URBAN CASE STUDY AREAS [129]—Continued

Benchmark level	Alternative standard level (ppb)	Average % children exposed [130]	Number of children (5 to 18 years) [number of asthmatic children] [131] [132]	Average % reduction from current standard [133]	% Children—worst year and worst area
	60	0–1.2	70,000 [8,000]	96	2.2
Two or more exposures of concern per season					
≥70 ppb	70	0–0.1	5,400 [600]	95	0.4
	65	0	300 [100]	100	0
	60	0	0 [0]	100	0
≥60 ppb	70	0.5–3.5	320,000 [35,000]	61	9.2
	65	0–0.8	67,000 [7,500]	92	2.8
	60	0–0.2	5,100 [700]	100	0.3

TABLE 5—SUMMARY OF ESTIMATED LUNG FUNCTION DECREMENTS FOR POTENTIAL ALTERNATIVE O_3 STANDARD LEVELS OF 70, 65, AND 60 PPB IN URBAN CASE STUDY AREAS

Lung function decrement	Alternative standard level	Average % children [136]	Number of children (5 to 18 years) [number of asthmatic children] [137] [138]	Average % reduction from current standard	% Children worst year and area
One or more decrements per season					
≥10%	70	11–17	2,527,000 [261,000]	15	20
	65	3–15	1,896,000 [191,000]	31	18
	60	5–11	1,404,000 [139,000] [139]	45	13
≥15%	70	2–4	562,000 [58,000]	26	5
	65	0–3	356,000 [36,000]	50	4
	60	1–2	225,000 [22,000]	67	3
≥20%	70	1–2	189,000 [20,000]	32	2.1
	65	0–1	106,000 [11,000]	59	1.4
	60	0–1	57,000 [6,000]	77	0.7
Two or more decrements per season					
≥10%	70	5.5–11	1,414,000 [145,000]	17	13
	65	1.3–8.8	1,023,000 [102,000]	37	11
	60	2.1–6.4	741,000 [73,000]	51	7.3
≥15%	70	0.9–2.4	276,000 [28,000]	29	3.1
	65	0.1–1.8	168,000 [17,000]	54	2.3
	60	0.2–1.0	101,000 [10,000]	71	1.4
≥20%	70	0.3–0.8	81,000 [8,000]	34	1.1
	65	0–0.5	43,000 [4,000]	66	0.8
	60	0–0.2	21,000 [2,000]	83	0.4

i. PA Consideration of an O_3 Standard Level of 70 ppb

The PA notes that a level of 70 ppb is below the lowest O_3 exposure concentration that has been reported to elicit a range of respiratory effects that includes AHR and decreased lung host defense, in addition to lung function decrements, airway inflammation, and respiratory symptoms (*i.e.,* 80 ppb). A level of 70 ppb is also below the lowest exposure concentration at which the combined occurrence of respiratory symptoms and lung function decrements have been reported (*i.e.,* 72 ppb), a combination judged adverse by the ATS (U.S. EPA, 2014c, section 3.1.3). A level of 70 ppb is above the lowest exposure concentration demonstrated to result in lung function decrements large enough to be judged an abnormal response by ATS and above the lowest exposure concentration demonstrated to result in pulmonary inflammation (*i.e.,* 60 ppb).

Compared to the current standard, the HREA estimates that a revised O_3

[136] Estimates in each urban case study area were averaged for the years evaluated in the HREA (2006 to 2010). Ranges reflect the ranges across urban study areas.

[137] Numbers of children estimated to experience decrements in each urban case study area were averaged over 2006 to 2010. These averages were then summed across urban study areas. Numbers are rounded to nearest thousand unless otherwise indicated.

[138] As noted in section II.C.3.a.ii, the responsiveness of asthmatics to O_3 exposures could depend on factors that have not been well-evaluated such as asthma severity, the effectiveness of asthma control, or the prevalence of medication use.

[139] As discussed in section 4.3.3 of the HREA (U.S. EPA, 2014a), the model-based air quality adjustment approach used to estimate risks associated with the current and alternative standards was unable to estimate the distribution of ambient O_3 concentrations in New York City upon just meeting an alternative standard with a level of 60 ppb. Therefore, for the 60 ppb standard level the numbers of children and asthmatic children reflect all of the urban study areas except New York.

standard with a level of 70 ppb would reduce exposures of concern to O_3 concentrations of 60, 70, and 80 ppb in urban study areas, with such a standard level estimated to be most effective at limiting exposures at or above the higher health benchmark concentrations and at limiting multiple occurrences of such exposures. On average over the years 2006 to 2010, for a standard with a level of 70 ppb, up to about 1% of children (*i.e.,* ages 5 to 18) are estimated to experience exposures of concern at or above 70 ppb (73% reduction, compared to current standard), and far less than 1% are estimated to experience two or more such exposures (95% reduction, compared to current standard). In the worst-case location and year (*i.e.,* location and year with the largest exposure estimate), about 3% of children are estimated to experience one or more exposures of concern at or above 70 ppb, and less than 1% are estimated to experience two or more. Far less than 1% of children are estimated to experience exposures of concern at or above the 80 ppb benchmark concentration, even in the worst-case year (Table 4, above).[140]

As noted above, CASAC advised the EPA that 60 ppb is an appropriate exposure of concern with respect to adverse effects on people with asthma, including children (Frey, 2014c, pp. 6 and 8). For an O_3 standard with a level of 70 ppb, about 3 to 10% of children, including asthmatic children, are estimated to experience one or more exposures of concern at or above 60 ppb in a single O_3 season. Compared to the current standard, this reflects about a 46% reduction, on average across the urban study areas. About 1% to 4% of children are estimated to experience two or more exposures of concern at or above 60 ppb (approximately 60% reduction, compared to current standard). In the worst-case location and year, for a standard set at 70 ppb, about 19% of children are estimated to experience one or more exposures of concern at or above 60 ppb, and 9% are estimated to experience two or more such exposures (Table 4, above).

Compared to the current standard, the HREA estimates that a revised O_3 standard with a level of 70 ppb would also reduce O_3-induced lung function decrements in children. A level of 70 ppb is estimated to be most effective at limiting the occurrences of moderate and large lung function decrements (*i.e.,* FEV_1 decrements ≥15% and ≥20%, respectively), and at limiting multiple occurrences of O_3-induced decrements. On average over the years 2006 to 2010, for a standard with a level of 70 ppb, about 2 to 4% of children in the urban study areas are estimated to experience one or more moderate O_3-induced lung function decrements (*i.e.,* FEV_1 decrement ≥15%), which would be of concern for healthy people, and about 1 to 2.5% of children are estimated to experience two or more such decrements (approximately 30% reduction, compared to the current standard). In the worst-case location and year, up to 5% of children are estimated to experience one or more O_3-induced lung function decrements ≥15%, and up to 3% are estimated to experience two or more such decrements. For a standard set at 70 ppb, about 2% or fewer children are estimated to experience large O_3-induced lung function decrements (*i.e.,* FEV_1 decrement ≥20%), and about 1% or fewer children are estimated to experience two or more such decrements, even in the worst-case years and locations (Table 5, above).

On average over the years 2006 to 2010, for an O_3 standard set at 70 ppb, about 11 to 17% of children in the urban study areas are estimated to experience one or more moderate O_3-induced lung function decrements (*i.e.,* FEV_1 decrement ≥10%), which could be adverse for people with lung disease. This reflects an average reduction of about 15%, compared to the current standard. About 6 to 11% of children are estimated to experience two or more such decrements (17% reduction, compared to current standard). In the worst-case location and year, for a standard set at 70 ppb, about 20% of children in the urban study areas are estimated to experience one or more O_3-induced lung function decrements ≥10%, and 13% are estimated to experience two or more such decrements (Table 5, above).

Compared to the current standard, a revised standard with a level of 70 ppb would also more effectively maintain short-term ambient O_3 concentrations below those present in the epidemiologic studies that reported significant O_3 health effect associations in locations likely to have met the current standard. In particular, the single-city study by Mar and Koenig (2009) reported positive and statistically significant associations with respiratory emergency department visits in children and adults in a location that likely would have met the current O_3 standard over the entire study period but violated a revised standard with a level of 70 ppb or below. None of the single-city studies evaluated in section 4.4.1 of the PA (U.S. EPA, 2014c) provide evidence for O_3 health effect associations in locations meeting a standard with a level of 70 ppb or below. While this analysis does not provide information on the extent to which the reported O_3-associated emergency department visits would persist upon meeting an O_3 standard with a level of 70 ppb, or on the extent to which standard levels below 70 ppb could further reduce the incidence of such emergency department visits,[141] it suggests that a revised O_3 standard with a level at or below 70 ppb would require reductions in the ambient O_3 concentrations that provided the basis for the health effect associations reported by Mar and Koenig (2009).

As discussed above, compared to single-city studies, there is greater uncertainty in linking air quality concentrations from individual study cities to multicity effect estimates. With regard to the multicity studies in this review, the PA notes that Dales et al. (2006) reported significant associations with respiratory hospital admissions based on air quality in 11 Canadian cities, most of which would likely have met the current standard over the entire study period, but violated a revised standard with a level of 70 ppb or below over at least part of that period (Table 4–1). This analysis suggests that although the current standard would allow the ambient O_3 concentrations in most of the study locations that provided the basis for the association with hospital admissions, a revised O_3 standard with a level at or below 70 ppb would require reductions in those ambient O_3 concentrations. As with the study by Mar and Koenig (2009), this analysis does not provide information on the extent to which the reported O_3-associated hospital admissions would persist upon meeting an O_3 standard with a level of 70 ppb, or on the extent to which standard levels below 70 ppb could further reduce the incidence of such hospital admissions.[142]

With regard to long-term O_3 concentrations, the PA evaluates the long-term O_3 metrics reported to be associated with mortality or morbidity in recent epidemiologic studies (*e.g.,*

[140] As noted above, due to interindividual variability, children (or adults) exposed at these levels will not necessarily experience health effects; the information available for some health effects is not sufficient to quantify the numbers of children in the urban study areas who might experience these effects.

[141] Put another way, one cannot infer from this analysis the extent to which effects would occur at O_3 concentrations below those observed in the study.

[142] In addition, for the other multicity studies identified in Table 4–1 of the PA (Cakmak et al., 2006; Stieb et al., 2009; Katsouyanni et al., 2009), and for the study by Bell et al. (2006) (for the 30 ppb cut point) (Table 4–2 of the PA), the majority of study locations would likely have met a standard with a level of 70 ppb (U.S. EPA, 2014c).

seasonal averages of 1-hour or 8-hour daily max concentrations). Compared to the current standard, a revised standard with a level of 70 ppb would be expected to reduce the risk of respiratory mortality associated with long-term O_3 concentrations, based on information from the study by Jerrett et al. (2009), though the PA notes the HREA conclusion, discussed above, that lower confidence should be placed in respiratory mortality risk estimates based on this study (U.S. EPA, 2014a, section 9.6). In addition, a standard with a level of 70 ppb would be expected to more effectively maintain long-term O_3 concentrations below those where the study by Jerrett et al. (2009) indicates the most confidence in the reported association with respiratory mortality.[143] Specifically, air quality analyses indicate this to be the case in 9 out of the 12 urban study areas for a level of 70 ppb, compared to 6 out of 12 areas for the current standard. Finally, a revised standard with a level of 70 ppb would be expected to reduce long-term O_3 concentrations based on the types of metrics that have been reported in recent epidemiologic studies to be associated with respiratory morbidity (*i.e.,* seasonal averages of daily maximum 8-hour concentrations).

In further considering the potential implications of epidemiology studies for alternative standard levels, the PA notes estimates of total mortality associated with short-term O_3 concentrations.[144] As discussed above, the PA considers estimates of total risk (*i.e.,* based on the full distributions of ambient O_3 concentrations) and estimates of risk associated with O_3 concentrations in the upper portions of ambient distributions. With regard to total risk the PA notes that, when summed across urban study areas, a standard with a level of 70 ppb is estimated to reduce the number of deaths associated with short-term O_3 concentrations by about 4% (2007) and 2% (2009), compared to the current standard.[145] Based on a national modeling analysis, the majority of the U.S. population would be expected to experience reductions in such risks upon reducing precursor emissions.

Compared to the total risk estimates noted above, an O_3 standard with a level of 70 ppb is estimated to be more effective at reducing the number of deaths associated with short-term O_3 concentrations at the upper ends of ambient distributions. Specifically, for area-wide O_3 concentrations at or above 40 ppb, a standard with a level of 70 ppb is estimated to reduce the number of deaths associated with short-term O_3 concentrations by about 10% compared to the current standard. In addition, for area-wide concentrations at or above 60 ppb, a standard with a level of 70 ppb is estimated to reduce O_3-associated deaths by about 50% to 70% (U.S. EPA, 2014c, Figure 4–13).

The PA noted that in providing the advice that 70 ppb is an appropriate upper bound for consideration, CASAC advised that a level of 70 ppb would provide little margin of safety for protection of public health, particularly for sensitive subpopulations (Frey, 2014c, p. 8). In particular, CASAC stated that:

> At 70 ppb, there is substantial scientific certainty of a variety of adverse effects, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety (Frey, 2014c, p. 8).[146]

However, the committee also acknowledged that ''the choice of a level within the range recommended based on scientific evidence [*i.e.,* 70 to 60 ppb] is a policy judgment under the statutory mandate of the Clean Air Act'' (Frey, 2014c, pp. ii and 8).

In summary, compared to the current standard, the PA concludes that a revised O_3 standard with a level of 70 ppb would be expected to (1) reduce the occurrence of exposures of concern to O_3 concentrations that result in respiratory effects in healthy adults (at or above 60 and 70 ppb) by about 45 to 95%, almost eliminating the occurrence of multiple exposures at or above 70 ppb; (2) reduce the occurrence of moderate-to-large O_3-induced lung function decrements (FEV_1 decrements ≥10, 15, 20%) by about 15 to 35%, most effectively limiting the occurrence of multiple decrements and decrements ≥15, 20%; (3) more effectively maintain short- and long-term O_3 concentrations below those present in the epidemiologic studies that reported significant O_3 health effect associations in locations likely to have met the current standard; [147] and (4) reduce the risk of O_3-associated mortality and morbidity, particularly the risk associated with the upper portions of the distributions of ambient O_3 concentrations.

ii. PA Consideration of an O_3 Standard Level of 65 ppb

The PA also considers a standard with a level of 65 ppb. A level of 65 ppb is well below 80 ppb, an O_3 exposure concentration that has been reported to elicit a range of respiratory effects that includes airway hyperresponsiveness and decreased lung host defense, in addition to lung function decrements, airway inflammation, and respiratory symptoms. A standard level of 65 ppb is also below the lowest exposure concentration at which the combined occurrence of respiratory symptoms and lung function decrements has been reported (*i.e.,* 72 ppb), a combination judged adverse by the ATS (U.S. EPA, 2014c, section 3.1.3). A level of 65 ppb is above the lowest exposure concentration demonstrated to result in lung function decrements large enough to be judged an abnormal response by ATS, where statistically significant changes in group mean responses would be judged to be adverse by ATS, and which the CASAC has indicated could be adverse in people with lung disease (*i.e.,* 60 ppb). A level of 65 ppb is also above the lowest exposure concentration at which pulmonary inflammation has been reported in healthy adults (*i.e.,* 60 ppb).

Compared to the current standard and a revised standard with a level of 70 ppb, the HREA estimates that a standard with a level of 65 ppb would reduce exposures of concern to the range of O_3 benchmark concentrations analyzed (*i.e.,* 60, 70, and 80 ppb). The HREA estimates that meeting a standard with a level of 65 ppb would eliminate exposures of concern at or above 80 ppb in the urban study areas. Such a standard is estimated to allow far less than 1% of children in the urban study areas to experience one or more exposures of concern at or above the 70

[143] As discussed in section 3.1.4.3 of the PA (U.S. EPA, 2014c), the study by Jerrett et al. (2009) suggests notably decreased confidence in the reported linear concentration-response function for long-term O_3 concentrations in the first quartile (*i.e.,* at or below about 53 ppb), given the widening in confidence intervals for lower concentrations; the fact that most study cities contributing to the linear function had O_3 concentrations in the highest three quartiles, accounting for approximately 72% of the respiratory deaths in the cohort (based on Table 2 in the published study); and the limited evidence presented in the published study for a threshold at or near 56 ppb.

[144] As discussed above, compared to the weight given to the evidence and to HREA estimates of exposures of concern and lung function risks, the PA places relatively less weight on epidemiologic-based risk estimates.

[145] A standard with a level of 70 ppb is also estimated to reduce respiratory mortality associated with long-term O_3 concentrations in urban study areas. However, given uncertainties associated with these risk estimates, as discussed above, the PA gives them limited weight.

[146] Also see Frey (2014c, p. ii).

[147] Epidemiologic studies also provide some evidence for O_3 health effect associations in locations likely to have met a standard with a level of 70 ppb, as discussed below for lower standard levels.

ppb benchmark level, even in the worst-case years and locations, and is estimated to eliminate the occurrence of two or more exposures at or above 70 ppb (Table 4, above).

In addition, for a standard with a level of 65 ppb, between 0 and about 4% of children (including asthmatic children) in urban study areas are estimated to experience exposures of concern at or above 60 ppb, which CASAC has indicated is an appropriate exposure of concern for people with asthma, including children. This reflects an 80% reduction (on average across areas), relative to the current standard. Less than 1% of children are estimated to experience two or more exposures of concern at or above 60 ppb (≤ 90% reduction, compared to current standard). In the worst-case location and year, about 10% of children are estimated to experience one or more exposures of concern at or above 60 ppb, with about 3% estimated to experience two or more such exposures (Table 4, above).

Compared to the current standard and a revised standard with a level of 70 ppb, the HREA estimates that a standard with a level of 65 ppb would also further reduce the occurrence of O_3-induced lung function decrements. For a level of 65 ppb, about 4% of children, or less, are estimated to experience moderate O_3-induced FEV_1 decrements ≥15% (50% reduction, compared to current standard), even considering the worst-case location and year. About 2% of children, or less, are estimated to experience two or more such decrements. Only about 1% of children, or less, are estimated to experience large O_3-induced lung function decrements (*i.e.,* FEV_1 decrement ≥20%), even in the worst-case year and location.

In addition, for a standard with a level of 65 ppb, about 3 to 15% of children are estimated to experience one or more moderate O_3-induced lung function decrements (*i.e.,* FEV_1 decrement ≥10%), which CASAC has indicated could be adverse for people with lung disease. This reflects an average reduction of about 30%, relative to the current standard. About 1 to 9% of children in the urban study areas are estimated to experience two or more such decrements (37% reduction, compared to current standard). In the worst-case location and year, for a standard set at 65 ppb, up to about 18% of these children are estimated to experience one or more moderate O_3-induced lung function decrements ≥10%, and up to 11% are estimated to experience two or more such decrements.

With regard to O_3 epidemiologic studies, the PA notes that a revised standard with a level of 65 ppb would be expected to maintain short-term ambient O_3 concentrations below those present in some of the study locations that provided the basis for reported O_3 health effect associations and that were likely to have met a revised standard with a level of 70 ppb. In particular, Katsouyanni et al. (2009) reported statistically significant associations with mortality based on air quality in 12 Canadian cities, most of which would likely have met a standard with a level of 70 ppb over the entire study period but violated a revised standard with a level of 65 ppb or below over at least part of that period (U.S. EPA, 2014c, Table 4–1). This analysis suggests that although the current standard or a standard with a level of 70 ppb would allow the ambient O_3 concentrations in most of the study locations that provided the basis for the association with mortality in this study, a revised O_3 standard with a level at or below 65 ppb would require reductions in those ambient O_3 concentrations. As discussed above for a level of 70 ppb, this analysis does not provide information on the extent to which O_3-associated mortality would persist upon meeting an O_3 standard with a level of 65 ppb, or on the extent to which standard levels below 65 ppb could further reduce the incidence of this mortality.[148]

With regard to long-term O_3 concentrations, as for 70 ppb (above) the PA evaluates the long-term O_3 metrics reported to be associated with mortality or morbidity in recent epidemiologic studies (*e.g.,* seasonal averages of 1-hour or 8-hour daily max concentrations). Compared to the current standard or a revised O_3 standard with a level of 70 ppb, a revised standard with a level of 65 ppb would be expected to further reduce the risk of respiratory mortality associated with long-term O_3 concentrations, based on information from the study by Jerrett et al. (2009).[149] In addition, a standard with a level of 65 ppb would be expected to more effectively maintain long-term O_3 concentrations below those where the study by Jerrett et al. (2009) indicates the most confidence in the reported association with respiratory mortality. Specifically, air quality analyses indicate this to be the case in 10 out of the 12 urban study areas for a level of 65 ppb, compared to 6 out of 12 areas for the current standard and 9 out of 12 for a standard with a level of 70 ppb (U.S. EPA, 2014c, Table 4–3). Finally, a revised standard with a level of 65 ppb would be expected to further reduce long-term O_3 concentrations based on the types of metrics that have been reported in recent epidemiologic studies to be associated with respiratory morbidity (*i.e.,* seasonal averages of daily maximum 8-hour concentrations).

In further considering the potential implications of epidemiology studies for alternative standard levels, the PA notes estimates of total mortality associated with short-term O_3.[150] As discussed above, the PA considers estimates of total risk (*i.e.,* based on the full distributions of ambient O_3 concentrations) and estimates of risk associated with O_3 concentrations in the upper portions of ambient distributions. With regard to total risk the PA notes that, when summed across urban study areas, a standard with a level of 65 ppb is estimated to reduce the number of deaths associated with short-term O_3 exposures by about 13% (2007) and 9% (2009), compared to the current standard.[151] For area-wide concentrations at or above 40 ppb, a standard level of 65 ppb is estimated to reduce O_3-associated deaths by almost 50% compared to the current standard, when summed across urban study areas. For area-wide concentrations at or above 60 ppb, a standard level of 65 ppb is estimated to reduce O_3-associated deaths by more than 80% (U.S. EPA, 2014c, Figure 4–13).

In summarizing CASAC's advice regarding a standard with a level of 65, the PA noted CASAC's conclusion that an alternative standard with a level of 65 ppb would further reduce, though not eliminate, the frequency of lung function decrements ≥15% and would lead to lower frequency of short-term premature mortality (*i.e.,* compared to a standard with a level of 70 ppb) (Frey, 2014c, p. 8).

In summary, compared to a standard with a level of 70 ppb, the PA concludes that a revised standard with a level of

[148] For the other multicity studies identified in Table 4–1 of the PA (Cakmak et al., 2006; Stieb et al., 2009; Katsouyanni et al., 2009 (for hospital admissions)), and for the study by Bell et al. (2006) (for the 30 ppb cut point) (Table 4–2 of the PA), the majority of study locations would have met a standard with a level of 65 ppb (U.S. EPA, 2014c).

[149] Though as discussed above, the PA notes the lower confidence placed in these risk results (U.S. EPA, 2014a, section 9.6).

[150] As discussed above, compared to the weight given to the evidence and to HREA estimates of exposures of concern and lung function risks, the PA places relatively less weight on epidemiologic-based risk estimates.

[151] A standard with a level of 65 ppb is also estimated to reduce respiratory mortality associated with long-term O_3 concentrations in urban study areas. However, given uncertainties associated with these risk estimates, as discussed above, we give them limited weight.

65 ppb would be expected to further reduce O_3 exposures and health risks. In particular, a standard with a level of 65 ppb is estimated to (1) reduce the occurrence of exposures of concern by about 80 to 100%, compared to the current standard, decreasing exposures at or above 60 ppb and almost eliminating exposures at or above 70 and 80 ppb; (2) reduce the occurrence of FEV_1 decrements ≥10, 15, and 20% by about 30 to 65%, compared to the current standard; (3) more effectively maintain short- and long-term O_3 concentrations below those present in the epidemiologic studies that reported significant O_3 health effect associations in locations likely to have met the current standard;[152] and (4) further reduce the risk of O_3-associated mortality and morbidity, particularly the risk associated with the upper portion of the distribution of ambient O_3 concentrations.

iii. PA Consideration of an O_3 Standard Level of 60 ppb

The PA also considers a standard with a level of 60 ppb. A level of 60 ppb is well below the O_3 exposure concentration that has been reported to elicit a wide range of potentially adverse respiratory effects in healthy adults (*i.e.,* 80 ppb). A level of 60 ppb is also below the lowest concentration where the combined occurrence of respiratory symptoms and lung function decrements was observed, a combination judged adverse by the ATS (*i.e.,* 72 ppb). A level of 60 ppb corresponds to the lowest exposure concentration demonstrated to result in lung function decrements that are large enough to be judged an abnormal response by ATS, that meet ATS criteria for adversity based on a downward shift in the distribution of FEV1, and that the CASAC indicated could be adverse in people with lung disease. A level of 60 ppb also corresponds to the lowest exposure concentration at which pulmonary inflammation has been reported in a single controlled human exposure study.

Based on the HREA analyses of O_3 exposures of concern, a standard with a level of 60 ppb is estimated to eliminate exposures of concern at or above the 70 and 80 ppb benchmark concentrations and to be more effective than the higher standard levels at limiting exposures of concern at or above 60 ppb. On average over the years 2006 to 2010, for a standard with a level of 60 ppb, between 0 and about 1% of children, including asthmatic children, in urban study areas are estimated to experience exposures of concern at or above 60 ppb, which CASAC indicated is an appropriate exposure of concern for asthmatic children. This reflects a 96% reduction (on average across areas), compared to the current standard. Virtually no children are estimated to experience two or more exposures of concern at or above 60 ppb. In the worst-case location and year, about 2% of children are estimated to experience exposures of concern at or above 60 ppb, with far less than 1% estimated to experience two or more such exposures (Table 4, above).

Based on the HREA analyses of O_3-induced lung function decrements, a standard with a level of 60 ppb would be expected to be more effective than a level of 65 or 70 ppb at limiting the occurrence of O_3-induced lung function decrements. For a standard with a level of 60 ppb, about 2% of children, or less, in the urban study areas are estimated to experience one or more moderate O_3-induced FEV_1 decrements ≥15% (almost 70% reduction, compared to current standard), and about 1% or less are estimated to experience two or more such decrements (3% in the location and year with the largest estimates). About 1% of children, or less, are estimated to experience large O_3-induced lung function decrements (*i.e.,* FEV_1 decrement ≥20%), even in the worst-case locations and year (Table 5, above).

In addition, for a standard with a level of 60 ppb, about 5 to 11% of children in the urban study areas are estimated to experience one or more moderate O_3-induced lung function decrements that CASAC indicated could be adverse for people with lung disease (*i.e.,* FEV_1 decrements ≥10%). This reflects an average reduction of about 45%, compared to the current standard. About 2 to 6% of children in these areas are estimated to experience two or more such decrements (51% reduction, compared to current standard). In the worst-case location and year, for a standard set at 60 ppb, up to about 13% of children are estimated to experience one or more moderate O_3-induced FEV_1 decrements ≥10%, and 7% are estimated to experience two or more such decrements (Table 5, above).

With regard to O_3 epidemiologic studies, the PA notes that a revised standard with a level of 60 ppb would be expected to maintain short-term ambient O_3 concentrations below those present in some of the study locations that provided the basis for reported O_3 health effect associations and that were likely to have met a revised standard with a level of 70 or 65 ppb. Specifically, in all of the U.S. and Canadian epidemiologic studies evaluated, the majority of study cities had ambient O_3 concentrations that would likely have violated a standard with a level of 60 ppb. Thus, none of the U.S. and Canadian epidemiologic studies analyzed provide evidence for O_3 health effect associations when the majority of study locations would likely have met a standard with a level of 60 ppb (U.S. EPA, 2014c, Tables 4–1 and 4–2). As discussed above, while this analysis does not provide information on the extent to which the O_3-associated morbidity or mortality would persist upon meeting an O_3 standard with a level of 60 ppb, it suggests that a revised O_3 standard with a level of 60 ppb would require reductions in the ambient O_3 concentrations that provided the basis for those health effect associations.

With regard to long-term O_3 concentrations, compared to the current standard or a revised O_3 standard with a level of 65 or 70 ppb, a revised standard with a level of 60 ppb would be expected to further reduce the risk of respiratory mortality associated with long-term O_3 concentrations, based on information from the study by Jerrett et al. (2009).[153] In addition, a standard with a level of 60 ppb would be expected to more effectively maintain long-term O_3 concentrations below those where the study by Jerrett et al. (2009) indicates the most confidence in the reported association with respiratory mortality. Specifically, air quality analyses indicate this to be the case in all of the urban study areas evaluated at a level of 60 ppb, compared to 6 out of 12 areas for the current standard, 9 out of 12 for a standard with a level of 70 ppb, and 10 out of 12 for a standard with a level of 65 ppb (U.S. EPA, 2014c, Table 4–3). Finally, a revised standard with a level of 60 ppb would be expected to further reduce long-term O_3 concentrations based on the types of metrics that have been reported in recent epidemiologic studies to be associated with respiratory morbidity (*i.e.,* seasonal averages of daily maximum 8-hour concentrations).

In further considering the potential implications of epidemiology studies for alternative standard levels, the PA notes estimates of total mortality associated with short-term O_3 concentrations.[154]

[152] Though epidemiologic studies also provide evidence for O_3 health effect associations in locations likely to have met a standard with a level of 65 ppb, as discussed below for a level of 60 ppb.

[153] Though as discussed above, the PA notes the lower confidence we place in these risk results (U.S. EPA, 2014a, section 9.6).

[154] As discussed above, compared to the weight given to the evidence and to HREA estimates of exposures of concern and lung function risks, we place relatively less weight on epidemiologic-based risk estimates.

As discussed above, the PA considers estimates of total risk (*i.e.,* based on the full distributions of ambient O_3 concentrations) and estimates of risk associated with O_3 concentrations in the upper portions of ambient distributions. With regard to total risk the PA notes that, when summed across urban study areas, a standard with a level of 60 ppb is estimated to reduce the number of deaths associated with short-term O_3 exposures by about 15% (2007) and 11% (2009), compared to the current standard (U.S. EPA, 2014c, Figure 4–13).[155] For area-wide concentrations at or above 40 ppb, a standard with a level set at 60 ppb is estimated to reduce O_3-associated deaths by almost 60% compared to the current standard. For area-wide concentrations at or above 60 ppb, a standard level of 60 ppb is estimated to reduce O_3-associated deaths by over 95% compared to the current standard.

In summary, compared to a standard with a level of 65 or 70 ppb, the PA concludes that a revised standard with a level of 60 ppb would be expected to further reduce O_3 exposures and health risks. In particular, a standard with a level of 60 ppb is estimated to (1) reduce the occurrence of exposures of concern by about 95 to 100%, compared to the current standard, almost eliminating exposures at or above 60 ppb; (2) reduce the occurrence of FEV_1 decrements ≥10, 15, and 20% by about 45 to 85%, compared to the current standard; (3) more effectively maintain short- and long-term O_3 concentrations below those present in the epidemiologic studies that reported significant O_3 health effect associations in locations likely to have met the current standard; [156] and (4) further reduce the risk of O_3-associated mortality and morbidity, particularly the risk associated with the upper portion of the distribution of ambient O_3 concentrations.

c. CASAC Advice

The PA recognizes that decisions regarding the weight to place on various types of evidence, exposure/risk information, and associated uncertainties reflect public health policy judgments that are ultimately left to the Administrator. To help inform those judgments with regard to the range of alternative primary O_3 standard levels appropriate for consideration, CASAC has provided advice to the Administrator based on their reviews of draft versions of the O_3 ISA, HREA, and PA. This section summarizes the advice provided by CASAC regarding alternative standard levels, as well as the views expressed at the CASAC meetings by public commenters. This section includes CASAC advice from the reconsideration of the 2008 final decision on the level of the standard, as well as CASAC advice received during the current review as it pertains to alternative standards.

Consistent with its advice in 2008, CASAC reiterated during the reconsideration its support for an 8-hour primary O_3 standard with a level ranging from 60 to 70 ppb, combined with the current indicator, averaging time, and form. Specifically, in response to the EPA's solicitation of CASAC advice during the reconsideration, the CASAC letter (Samet, 2010) to the Administrator stated:

> CASAC fully supports EPA's proposed range of 0.060–0.070 parts per million (ppm) for the 8-hour primary ozone standard. CASAC considers this range to be justified by the scientific evidence as presented in the Air Quality Criteria for Ozone and Related Photochemical Oxidants (March 2006) and Review of the National Ambient Air Quality Standards for Ozone: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper (July 2007).

Similarly, in response to the EPA's request for additional advice on the reconsideration in 2011, CASAC reaffirmed its conclusion that ''the evidence from controlled human and epidemiologic studies strongly supports the selection of a new primary ozone standard within the 60–70 ppb range for an 8-hour averaging time'' (Samet, 2011). CASAC further concluded that this range ''would provide little margin of safety at its upper end'' (Samet, 2011, p. 2).

In the current review of the Second Draft PA, CASAC concurred with staff's conclusions that it is appropriate to consider retaining the current indicator (O_3), averaging time (8-hour average) and form (3-year average of the 4th highest maximum daily 8-hour average. With regard to level, CASAC stated the following (Frey, 2014c, pp. ii to iii):

> The CASAC further concludes that there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb. The CASAC reached this conclusion based on the scientific evidence from clinical studies, epidemiologic studies, and animal toxicology studies, as summarized in the Integrated Science Assessment (ISA), the findings from the exposure and risk assessments as summarized in the HREA, and the interpretation of the implications of these sources of information as given in the Second Draft PA.
>
> The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence [*i.e.,* 70 to 60 ppb] is a policy judgment under the statutory mandate of the Clean Air Act. The CASAC advises that, based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations.
>
> Thus, our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety.

The public commenters who expressed the view that the current primary O_3 standard is not adequate (II.D.3) also submitted comments that supported revising the level of the primary O_3 standard. Several of these commenters expressed the view that the level should be revised to the lower end of the range of 70 to 60 ppb, or in some cases to a level below 60 ppb. These commenters often placed a large amount of emphasis on evidence from controlled human exposure studies for respiratory effects following exposures to 60 ppb O_3.

In addition, as discussed above (II.D.3), some public commenters expressed the view that revision of the current standard is not necessary. Consistent with their view that it would not be appropriate to revise the current standard, these commenters did not provide any provisional views on alternative levels below 75 ppb that would be appropriate for consideration.

d. Administrator's Proposed Conclusions on Level

This section discusses the Administrator's proposed conclusions on the level of the primary O_3 standard. In conjunction with her proposed decisions to retain the current indicator, averaging time, and form (II.E.1 to II.E.3, above), the Administrator proposes to revise the level of the primary O_3 standard to within the range of 65 to 70 ppb. In doing so, she is mindful that the selection of a primary O_3 standard that is requisite to protect public health with an adequate margin of safety requires judgments based on an interpretation of the scientific evidence and exposure/risk information that neither overstates nor understates the strengths and limitations of that evidence and information, nor the appropriate

[155] A standard with a level of 60 ppb is also estimated to reduce respiratory mortality associated with long-term O_3 concentrations in urban study areas. However, given uncertainties associated with these risk estimates, as discussed above, the PA gives them limited weight.

[156] As discussed above, these studies do not provide information on the extent to which O_3 health effect associations would persist following reductions in ambient O_3 concentrations in order to meet a standard with a level of 60 ppb.

inferences to be drawn therefrom.[157] The rationale supporting the Administrator's proposed conclusions on alternative standard levels is discussed below.

The Administrator's proposed conclusions on alternative standard levels build upon her proposed conclusion that the overall body of scientific evidence and exposure/risk information call into question the adequacy of public health protection afforded by the current primary O_3 standard, particularly for at-risk populations and lifestages (II.D.5). These proposed conclusions are based on consideration of the scientific evidence assessed in the ISA (U.S. EPA, 2013a); the results of the exposure and risk assessments in the HREA (U.S. EPA, 2014a); the evidence-based and exposure-/risk-based considerations and conclusions in the PA (U.S. EPA, 2014c); CASAC advice and recommendations, as reflected in CASAC's letters to the Administrator and in public discussions of drafts of the ISA, HREA, and PA; and public input received during the development of these documents.

In reaching proposed conclusions on alternative levels for the primary O_3 standard, the Administrator considers the extent to which various alternatives would be expected to protect the public, including at-risk populations, against the wide range of adverse health effects that have been linked with short- or long-term O_3 exposures. At-risk populations include people with asthma; children and older adults; people who are active outdoors, including outdoor workers; people with certain genetic variants; and people with reduced intake of certain nutrients.

As was the case for her consideration of the adequacy of the current primary O_3 standard (II.D.5), the Administrator places the greatest weight on the results of controlled human exposure studies and on exposure and risk analyses based on information from these studies. In doing so, she notes that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following exposures to specific O_3 concentrations. The effects reported in these studies are due solely to O_3 exposures, and interpretation of study results is not complicated by the presence of co-occurring pollutants or pollutant mixtures (as is the case in epidemiologic studies). She further notes the CASAC judgment that ''the scientific evidence supporting the finding that the current standard is inadequate to protect public health is strongest based on the controlled human exposure studies of respiratory effects'' (Frey, 2014c, p. 5). Consistent with this emphasis, the HREA conclusions reflect relatively greater confidence in the results of the exposure and risk analyses based on information from controlled human exposure studies (*i.e.,* exposures of concern and risk of lung function decrements) than the results of epidemiology-based risk analyses, given the greater uncertainties in the epidemiology-based risk estimates (U.S. EPA, 2014a, section 9.6). For all of these reasons, the Administrator has the most confidence in using the information from controlled human exposure studies to reach proposed conclusions on alternative standard levels.

In considering the evidence from controlled human exposure studies, the Administrator first notes that these studies have reported a variety of respiratory effects in healthy adults following exposures to O_3 concentrations of 60,[158] 72,[159] or 80 ppb, and higher. The largest respiratory effects, and the broadest range of effects, have been studied and reported following exposures of healthy adults to 80 ppb O_3 or higher, with most exposure studies conducted at these higher concentrations. Exposures of healthy adults to O_3 concentrations of 80 ppb or higher have been reported to decrease lung function, increase airway inflammation, increase respiratory symptoms, result in airway hyperresponsiveness, and decrease lung host defenses (II.B.2).

The Administrator notes that O_3 exposure concentrations as low as 72 ppb have been shown to both decrease lung function and increase respiratory symptoms (Schelegle et al., 2009), a combination that meets the ATS criteria for an adverse response. In considering effects at 72 ppb, CASAC likewise noted that ''the combination of decrements in FEV_1 together with the statistically significant alterations in symptoms in human subjects exposed to 72 ppb ozone meets the American Thoracic Society's definition of an adverse health effect'' (Frey, 2014c, p. 5).

With regard to lower exposure concentrations, the Administrator notes that the combination of statistically significant increases in respiratory symptoms and decrements in lung function has not been reported. More specifically, she notes that respiratory symptoms have been evaluated following 6.6-hour exposures to average O_3 concentrations of 60 ppb (Adams, 2006; Kim et al., 2011) and 63 ppb (Schelegle et al., 2009) and that none of these studies reported a statistically significant increase in respiratory symptoms, compared to filtered air controls.[160]

Based on this evidence, the Administrator reaches the initial conclusion that the results of controlled human exposure studies strongly support setting the level of a revised O_3 standard no higher than 70 ppb. In reaching this initial conclusion, the Administrator places a large amount of weight on the importance of setting the level of the standard well below 80 ppb, the O_3 exposure concentration shown in healthy adults to result in the broadest range of respiratory effects, and below 72 ppb, the lowest O_3 exposure concentration shown in healthy adults to result in the adverse combination of respiratory symptoms and lung function decrements.

In further considering the potential public health implications of a standard with a level of 70 ppb, the Administrator also considers the extent to which such a standard would be expected to limit population exposures to the broader range of O_3 concentrations reported in controlled human exposure studies to cause respiratory effects. Given the range of effects reported following exposures to 80 ppb O_3, and the evidence for the adverse combination of lung function decrements and respiratory symptoms in healthy adults following exposures as low as 72 ppb, the Administrator concludes that the evidence in this review supports the occurrence of adverse respiratory effects for exposures to O_3 concentrations at or above 72 ppb.

The Administrator has decreasing confidence that adverse effects will occur following exposures to O_3 concentrations below 72 ppb. In particular, compared to O_3 exposure

[157] As discussed above (I.B), in addressing the requirement for an adequate margin of safety the EPA considers such factors as the nature and severity of the health effects, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach for providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. See *Lead Industries Association* v. *EPA,* 647 F. 2d at 1161–62; *State of Mississippi,* 744 F. 3d at 1353.

[158] As discussed above (II.B.2), exposures to 60 ppb O_3 have been evaluated in studies by Adams (2002, 2006), Schelegle et al. (2009), and Kim et al. (2011). In the study by Schelegle, for the 60 ppb target exposure concentration, study authors reported that the actual mean exposure concentration was 63 ppb.

[159] As noted above, for the 70 ppb target exposure concentration, Schelegle et al. (2009) reported that the actual mean exposure concentration was 72 ppb.

[160] However, following exposures to 60 ppb O_3, several studies have observed decreases in lung function and one study (Kim et al., 2011) observed an increase in airway inflammation (II.B.2).

concentrations at or above 72 ppb, she has less confidence that adverse effects will occur following exposures to O_3 concentrations as low as 60 ppb. In reaching this conclusion, she notes that, as discussed above, statistically significant increases in respiratory symptoms, combined with lung function decrements, have not been reported following exposures to 60 or 63 ppb O_3, though several studies have evaluated the potential for such effects.

Although she has decreasing confidence in the occurrence of adverse effects following exposures to O_3 concentrations below 72 ppb, the Administrator notes the CASAC judgment that the adverse combination of lung function decrements and respiratory symptoms ''almost certainly occur in some people'' following exposures to lower concentrations (Frey, 2014c, p. 6). In particular, when commenting on the extent to which the study by Schelegle et al. (2009) suggests the potential for adverse effects following O_3 exposures below 72 ppb, CASAC judged that:

> [I]f subjects had been exposed to ozone using the 8-hour averaging period used in the standard [*i.e.,* rather than the 6.6 hour exposures evaluated in the study], adverse effects could have occurred at lower concentration. Further, in our judgment, the level at which adverse effects might be observed would likely be lower for more sensitive subgroups, such as those with asthma [*i.e.,* compared to the healthy adults evaluated in the study] (Frey, 2014c, p. 5).

Though CASAC did not provide advice as to how far below 72 ppb adverse effects would likely occur, the Administrator agrees that such effects could occur following exposures at least somewhat below 72 ppb.

Based on the evidence and CASAC advice noted above, when considering the extent to which a standard with a level of 70 ppb would be expected to limit population exposures to the broader range of O_3 concentrations shown to cause respiratory effects, the Administrator considers the extent to which such a standard would be expected to limit the occurrence of O_3 exposures of concern at or above 60, 70, and 80 ppb.[161] In doing so, she notes that an O_3 standard established at a particular level can provide protection against a range of exposure concentrations, including concentrations below the standard level. This is because the degree of protection provided by any NAAQS is due to the combination of all of the elements of the standard (*i.e.,* indicator, averaging time, form, level). In the case of the 4th maximum form of the O_3 NAAQS, which the Administrator is proposing to retain in the current review (II.E.3), the large majority of days in areas that meet the standard will have 8-hour O_3 concentrations below the level of the standard.

In considering exposures of concern at or above 60, 70, and 80 ppb, the Administrator judges that the evidence supporting the occurrence of adverse respiratory effects is strongest for exposures at or above the 70 and 80 ppb benchmarks. While the Administrator has less confidence that adverse effects will occur following exposures to O_3 concentrations as low as 60 ppb, she notes the possibility for adverse effects following such exposures given that (1) CASAC has indicated the moderate lung function decrements (*i.e.,* FEV_1 decrements ≥10%) that occur in some healthy adults following exposures to 60 ppb O_3, which are large enough to be judged an abnormal response by ATS, could be adverse to people with lung disease (II.B.3), and that (2) airway inflammation has been reported following exposures as low as 60 ppb O_3. She also takes note of CASAC advice that the occurrence of exposures of concern at or above 60 ppb is an appropriate consideration for people (including children) with asthma (Frey, 2014c, p. 6).

Due to interindividual variability in responsiveness, the Administrator further notes that not every occurrence of an exposure of concern will result in an adverse effect.[162] Repeated occurrences of some of the effects demonstrated following exposures of concern could increase the likelihood of adversity. For example, as discussed in the ISA (U.S. EPA, 2013a, Section 6.2.3), repeated occurrences of airway inflammation could lead to the induction of a chronic inflammatory state; altered pulmonary structure and function, leading to diseases such as asthma; altered lung host defense response to inhaled microorganisms, particularly in potentially at-risk populations such as the very young and old; and altered lung response to other agents such as allergens or toxins. The Administrator notes that the types of lung injury that can occur following exposures of concern, particularly if experienced repeatedly, provide a plausible mode of action by which O_3 may cause other more serious effects. Therefore, the Administrator is most concerned about protecting at-risk populations against repeated occurrences of exposures of concern.

Based on the above considerations, the Administrator focuses on the extent to which a revised standard would be expected to protect populations from experiencing two or more O_3 exposures of concern (*i.e.,* as a surrogate for repeated exposures). While she emphasizes the importance of limiting two or more exposures and reducing their occurrence, compared to the current standard, she balances this emphasis by noting that (1) not all exposures of concern will result in adverse effects; (2) she has less confidence in the occurrence of adverse effects at the 60 ppb benchmark than at the 70 or 80 ppb benchmarks; and (3) the NAAQS are not meant to be zero-risk standards.[163] Therefore, in using estimates of exposures of concern to inform her decisions on alternative standard levels, the Administrator judges that it would not be appropriate to set a standard intended to eliminate all exposures of concern for all benchmarks, particularly the 60 ppb benchmark. Her consideration of specific estimates of exposures of concern is discussed below.

As illustrated in Table 1 (above), the Administrator notes that, in urban study areas, a revised standard with a level of 70 ppb would be expected to eliminate the occurrence of two or more exposures of concern to O_3 concentrations at and above 80 ppb and to virtually eliminate the occurrence of two or more exposures of concern to O_3 concentrations at and above 70 ppb, even in the worst-case urban study area and year. For the 70 ppb benchmark, this reflects about a 95% reduction in the occurrence of two or more exposures of concern, compared to the current standard (Table 4).

Though the Administrator acknowledges greater uncertainty with regard to the occurrence of adverse effects following exposures of concern at or above 60 ppb, she notes that a revised standard with a level of 70 ppb would also be expected to protect the large majority of children in the urban study areas (*i.e.,* about 96% to more

[161] As with her consideration of the current standard (II.D.5), the Administrator focuses on estimated exposures of concern in children, including asthmatic children, noting the HREA analyses indicating that exposures of concern occur in a larger percentage of children than adults (given that a larger percentage of children are estimated to spend an extended period of time being physically active outdoors when O_3 concentrations are elevated) (II.C.2). To the extent alternative standards provide an appropriate degree of protection for children, she judges that those standards will also protect adult populations (including at-risk adult populations).

[162] For most of the effects demonstrated in controlled human exposure studies (*e.g.,* airway inflammation, AHR, decreased lung host defense, respiratory symptoms) the available data are not sufficient to quantify the number of people who would experience adverse effects due to O_3 exposures.

[163] *State of Mississippi,* 744 F. 3d at 1343.

than 99% of children in individual urban study areas) from experiencing two or more exposures of concern at or above 60 ppb. Compared to the current standard, this represents a reduction of more than 60% in the occurrence of two or more exposures of concern (Tables 1 and 4).

Based on the above information, the Administrator concludes that a revised O_3 standard with a level of 70 ppb would be expected to virtually eliminate the occurrence of two or more O_3 exposures of concern for the 70 and 80 ppb benchmarks, and to substantially reduce the occurrence of two or more O_3 exposures of concern for the 60 ppb benchmark, compared to the current standard.

Although the Administrator is less concerned about single occurrences of exposures of concern, she acknowledges that even single exposures to O_3 concentrations at or above benchmark concentrations (particularly for the 70 and 80 ppb benchmarks) could potentially result in adverse effects. To the extent this may be the case, the Administrator notes that a standard with a level of 70 ppb would also be expected to (1) virtually eliminate all occurrences of exposures of concern at or above 80 ppb, even in the worst-case year and location and (2) achieve important reductions, compared to the current standard, in the occurrence of one or more exposures of concern at or above 70 and 60 ppb (*i.e.,* about a 70% reduction for the 70 ppb benchmark and almost a 50% reduction for the 60 ppb benchmark) (Tables 1 and 4).

In further evaluating the potential public health impacts of a standard with a level of 70 ppb, the Administrator also considers the HREA estimates of O_3-induced lung function decrements. To inform her consideration of these decrements, the Administrator takes note of CASAC advice that ''estimation of FEV_1 decrements of ≥15% is appropriate as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, whereas an FEV_1 decrement of ≥10% is a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease'' (Frey, 2014c, p. 3). Consistent with this advice, she considers estimates of the occurrence of O_3-induced FEV_1 decrements ≥10 and 15% as surrogates for the occurrence of adverse health outcomes.

While these surrogates provide perspective on the potential for the occurrence of adverse respiratory effects following O_3 exposures, the Administrator agrees with the conclusion in past reviews that a more general consensus view of the adversity of moderate responses emerges as the frequency of occurrence increases (61 FR 65722–3) (Dec. 13, 1996). Specifically, she concludes that not every estimated occurrence of an O_3-induced FEV_1 decrement will be adverse and that repeated occurrences of moderate responses, even in otherwise healthy individuals, may be considered to be adverse since they could set the stage for more serious illness. Therefore, the Administrator becomes increasingly concerned about the potential for adversity as the frequency of occurrences increases and, as a result, she focuses primarily on estimates of two or more O_3-induced FEV_1 decrements (*i.e.,* as a surrogate for repeated exposures).

Given the above considerations, the Administrator does not believe it would be appropriate to set a standard that is intended to eliminate all O_3-induced FEV_1 decrements. She notes that this is consistent with CASAC advice, which did not include a recommendation to set the standard level low enough to eliminate all O_3-induced FEV_1 decrements ≥10 or 15% (Frey, 2014c). Rather, the Administrator considers the extent to which a standard with a level of 70 ppb would be expected to protect the population from experiencing O_3-induced FEV_1 decrements ≥10 and 15%, including the extent to which such a standard would be expected to achieve reductions in the occurrence of O_3-induced FEV_1 decrements, relative to the current standard.[164]

The Administrator notes that a revised O_3 standard with a level of 70 ppb is estimated to protect about 98 to 99% of children in urban study areas from experiencing two or more O_3-induced FEV_1 decrements ≥15%, and about 89 to 94% from experiencing two or more decrements ≥10%.[165] Compared to the current standard, these estimates represent decreases in the occurrence of two or more O_3-induced decrements of about 29 and 17%, respectively (Tables 2 and 5). Although the Administrator is less concerned about the public health implications of single O_3-induced lung function decrements, she also gives some consideration to estimates of one or more O_3-induced FEV_1 decrements. In particular, she notes that a revised standard with a level of 70 ppb is estimated to reduce the occurrence of one or more O_3-induced decrements, compared to the current standard, by about 26% (for decrements ≥15%) and 15% (for decrements ≥10%) (Tables 2 and 5).

Given all of the above information, the Administrator concludes that a revised standard with a level of 70 ppb would be expected to provide substantial protection against O_3 exposures of concern (for benchmark concentrations of 60, 70, 80 ppb) and O_3-induced lung function decrements, and would be expected to result in important reductions in the occurrence of such exposures and decrements, compared to the current standard. This is particularly the case for estimates of two or more occurrences of exposures of concern and lung function decrements.

In next considering the additional protection that would be expected from standard levels below 70 ppb, the Administrator evaluates the extent to which a standard with a level of 65 ppb would be expected to further limit O_3 exposures of concern and O_3-induced lung function decrements.

In addition to eliminating almost all exposures of concern to O_3 concentrations at or above 80 and 70 ppb, even in the worst-case years and locations, the Administrator notes that a revised standard with a level of 65 ppb would be expected to protect more than 99% of children in urban study areas (and 100% of children in some urban study areas) from experiencing two or more exposures of concern at or above 60 ppb. Compared to the current standard, this represents about a 95% reduction in the occurrence of two or more exposures of concern for the 60 ppb benchmark (Tables 1 and 4). In addition, the Administrator notes that a revised standard with a level of 65 ppb is estimated to reduce the occurrence of one or more exposures of concern for the 60 ppb benchmark by about 80%, compared to the current standard (Tables 1 and 4).

With regard to O_3-induced lung function decrements, the Administrator notes that an O_3 standard with a level of 65 ppb is estimated to protect about 98% to more than 99% of children from experiencing two or more O_3-induced FEV_1 decrements ≥15%, even considering the worst-case year and location, and about 91 to 99% from

[164] The Administrator additionally notes that, unlike exposures of concern, the variability in lung function risk estimates across urban study areas is often greater than the differences in risk estimates between various standard levels (Table 2, above). Given this, and the resulting considerable overlap between the ranges of lung function risk estimates for different standard levels, although the Administrator has confidence in the lung function risk estimates themselves, she views them as providing a more limited basis than exposures of concern for distinguishing between the degree of public health protection provided by alternative standard levels.

[165] In the worst-case year and location, a standard with a level of 70 ppb is estimated to protect about 97% of children in urban study areas from experiencing two or more O_3-induced FEV_1 decrements ≥15%, and about 87% from experiencing two or more decrements ≥10%.

experiencing two or more decrements ≥10% (89% in worst-case year and location). These estimates reflect reductions, compared to the current standard, of about 54 and 37%, respectively. A revised standard with a level of 65 ppb is also estimated to reduce the occurrence of one or more lung function decrements ≥15 and 10%, compared to the current standard, by about 50 and 31%, respectively.

Taken together, the Administrator initially concludes that the evidence from controlled human exposure studies, and the information from quantitative analyses that draw upon these studies (*i.e.,* exposures of concern, O_3-induced FEV_1 decrements), provide strong support for standard levels from 65 to 70 ppb. In particular, she bases this conclusion on the fact that such standard levels would be well below the O_3 exposure concentration shown to result in the widest range of respiratory effects (*i.e.,* 80 ppb), and below the lowest O_3 exposure concentration shown to result in the adverse combination of lung function decrements and respiratory symptoms (*i.e.,* 72 ppb). A standard with a level from 65 to 70 ppb would also be expected to result in important reductions, compared to the current standard, in the occurrence of O_3 exposures of concern for all of the benchmarks evaluated (*i.e.,* 60, 70, and 80 ppb) and in the risk of O_3-induced lung function decrements ≥10 and 15%.

In further considering the evidence and exposure/risk information, the Administrator considers the extent to which the epidemiologic evidence, and the quantitative risk estimates based on information from epidemiologic studies, also provide support for standard levels from 65 to 70 ppb. In doing so, as in her consideration of the adequacy of the current O_3 standard, the Administrator focuses on epidemiologic studies of respiratory-related hospital admissions, emergency department visits, and mortality. These considerations are discussed below.

The Administrator first considers the extent to which available epidemiologic studies have reported associations between short-term O_3 concentrations and emergency department visits, hospital admissions, and/or mortality in locations that would likely have met alternative standards with levels from 65 to 70 ppb (U.S. EPA, 2014c, section 4.4.1). In evaluating the epidemiologic evidence in this way, the Administrator places the most weight on single-city studies of short-term O_3 concentrations, recognizing that there were no multicity studies for which air quality data indicated that all cities included in the analyses would likely have met alternative standard levels. In particular, she notes that while single-city studies are more limited than multicity studies in terms of statistical power and geographic coverage, conclusions linking air quality in a given city with health effect associations in that same city can be made with greater certainty for single-city studies of short-term O_3, compared to health effect associations aggregated across multiple cities in multicity studies. In particular, the Administrator notes considerable uncertainty in linking multicity effect estimates (aggregated across multiple cities) for short-term O_3 with the air quality for subsets of study locations (rather than all locations) likely to have met an alternative standard.[166]

Given the above, the Administrator notes analyses in the PA (U.S. EPA, 2014c, section 4.4.1) indicating that a revised standard with a level of 65 or 70 ppb would be expected to maintain short-term ambient O_3 concentrations below those present in the locations of all of the single-city studies analyzed. As discussed in the PA (U.S. EPA, 2014c, section 4.4.1), this includes several single-city studies conducted in locations that would have violated the current standard, and the single-city study by Mar and Koenig (2009) that reported positive and statistically significant associations with respiratory emergency department visits with children and adults in a location that likely would have met the current standard over the entire study period but that would likely not have met a revised standard with a level of 70 ppb or below. Thus, the Administrator notes that, while the current standard would allow the ambient O_3 concentrations that provided the basis for the health effect associations reported by Mar and Koenig (2009), a revised O_3 standard with a level at or below 70 ppb would require reductions in those ambient O_3 concentrations. While the Administrator acknowledges uncertainty in the extent to which the reported O_3-associated emergency department visits could be further reduced by standard levels below 65 or 70 ppb, she concludes that this analysis indicates that a revised standard with a level at least as low as 70 ppb would result in improvements in public health, beyond the protection provided by the current standard, in the locations of the single-city epidemiologic studies that reported significant health effect associations.

As discussed above, the Administrator notes the greater uncertainty in interpreting air quality in locations of multicity epidemiologic studies of short-term O_3 for the purpose of evaluating alternative standard levels (II.D.1 and U.S. EPA, 2014c, section 4.4.1). Therefore, she places less weight on these studies than on the single-city studies noted above. Despite this uncertainty, she notes that PA analyses suggest that standard levels of 65 or 70 ppb would require additional reductions, beyond those required by the current standard, in ambient O_3 concentrations in several of the epidemiologic study locations that provided the basis for statistically significant O_3 health effect associations. For example, she notes that Dales et al. (2006) reported significant associations with respiratory hospital admissions based on air quality in 11 Canadian cities, most of which would likely have met the current standard over the entire study period (*i.e.,* seven cities) but would have violated a standard with a level of 70 ppb or below over at least part of that period (U.S. EPA, 2014c, Table 4–1). She further notes that Katsouyanni et al. (2009) reported statistically significant associations with mortality based on air quality in 12 Canadian cities, most of which would likely have met the current standard (*i.e.,* eight study cities) and a standard with a level of 70 ppb (*i.e.,* seven study cities) over the entire study period, but would have violated a standard with a level of 65 ppb over at least part of that period (U.S. EPA, 2014c, Table 4–1). While most of the other multicity epidemiologic studies evaluated also suggest that a level from 65 to 70 ppb would result in public health improvements, compared to the current standard, the Administrator acknowledges that several multicity epidemiologic studies reported O_3 health effect associations when the majority of study cities would likely

[166] In recognizing that multicity studies are often emphasized over single-city studies for purposes of making weight of evidence judgments (U.S. EPA, 2013a), the Administrator's judgment in this case applies specifically to interpreting air quality analyses for epidemiologic studies of short-term O_3 concentrations where multicity effect estimates are aggregated across cities, and where individual city effect estimates are not presented (as is the case for the key O_3 studies analyzed in the PA, with the exception of the study by Stieb et al. (2009) where none of the city-specific effect estimates for asthma emergency department visits were statistically significant). Because reported multicity effect estimates do not allow health effect associations to be disaggregated by individual city, it is not possible to assign the multicity health effect association to the air quality in any one study location, or to the air quality in a particular subset of locations. In contrast, for epidemiologic studies of long-term concentrations, where multicity effect estimates are based on comparisons across cities, different judgments have been made by EPA with regard to the utility of multicity studies (see, *e.g.* 78 FR 3086 at 3103/2, January 15, 2013) (and see discussion below of study by Jerrett et al., 2009).

have met standards with levels from 65 to 70 ppb. However, given the important uncertainties in interpreting the air quality in these multicity studies, the Administrator places limited weight on them overall, relative to the single-city studies noted above (and relative to the information based on controlled human exposure studies).

With regard to long-term O_3 concentrations, the Administrator considers the long-term O_3 metrics reported to be associated with mortality or morbidity in recent epidemiologic studies (*e.g.,* seasonal averages of 1-hour or 8-hour daily max concentrations). Compared to the current standard, she notes that analyses in the PA (U.S. EPA, 2014c, section 4.4.1) suggest a revised standard with a level of 65 or 70 ppb would more effectively maintain long-term O_3 concentrations below those where the multicity study by Jerrett et al. (2009) indicates the most confidence in the reported association with respiratory mortality (II.B.2, II.D.1). Based on additional information from the study by Jerrett et al. (2009), the Administrator also notes HREA analyses indicating that a revised standard with a level of 65 or 70 ppb would be expected to reduce the risk of respiratory mortality associated with long-term O_3 concentrations (though she also notes important uncertainties with these risk estimates, as described below). Finally, she notes analyses in the HREA suggesting that a revised standard with a level of 65 or 70 ppb would be expected to reduce long-term O_3 concentrations, defined in terms of O_3 metrics similar to the long-term metrics that have been reported in recent epidemiologic studies to be associated with respiratory morbidity (*i.e.,* seasonal averages of daily maximum 8-hour concentrations). Given the above evidence and information, the Administrator concludes that a revised 8-hour standard with a level from 70 to 65 ppb could increase public health protection, compared to the current standard, against effects associated with long-term O_3 exposures.

In further evaluating information from epidemiologic studies, the Administrator also considers the HREA's epidemiology-based risk estimates of morbidity and mortality associated with short-term O_3 (U.S. EPA, 2014a). Compared to the weight given to the evidence from controlled human exposure studies, and to HREA estimates of exposures of concern and lung function risks, she places relatively less weight on epidemiology-based risk estimates. In doing so, she notes that the overall conclusions from the HREA likewise reflect relatively less confidence in estimates of epidemiology-based risks than in estimates of exposures of concern and lung function risks. As discussed above (II.C.3.b), this is based on the greater uncertainties associated with mortality and morbidity risk estimates, including the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions at lower O_3 concentrations. The Administrator further notes the HREA conclusion that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study (even though that study is well-designed) and because of the uncertainty in that study regarding the existence and identification of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6).

In considering epidemiology-based risk estimates, the Administrator focuses on the extent to which potential alternative O_3 standards are estimated to reduce the risk of mortality associated with short-term exposures to O_3, noting the similar patterns of risk across urban study areas and air quality scenarios for respiratory morbidity endpoints (II.C.3). Given the uncertainties in epidemiology-based risk estimates, the Administrator focuses on the general magnitudes of risk changes estimated for standard levels of 65 and 70 ppb, compared to the current standard, rather than placing a large amount of weight on the absolute estimates of O_3-associated deaths. In doing so, she notes the CASAC conclusion that ''[a]lthough the estimates for short-term exposure impacts are subject to uncertainty, the data supports a conclusion that there are meaningful reductions in mean premature mortality associated with ozone levels lower than the current standard'' (Frey, 2014a, p. 10). She further notes that, as discussed above (II.C.3.b), the HREA risk estimates for urban study areas are likely to understate the average reductions in O_3-associated mortality and morbidity risks that would be experienced across the U.S. population as a whole upon meeting standards with lower levels.

The Administrator's primary focus is on risks associated with O_3 concentrations in the upper portions of ambient distributions, given the greater uncertainty associated with the shapes of concentration-response curves for O_3 concentrations in the lower portions of ambient distributions.[167] The Administrator further notes that experimental studies provide the strongest evidence for O_3-induced effects following exposures to O_3 concentrations corresponding to the upper portions of typical ambient distributions. In particular, as discussed above, she notes controlled human exposure studies showing respiratory effects following exposures to O_3 concentrations at or above 60 ppb (II.B).

In considering risks associated with O_3 concentrations in the upper portions of ambient distributions, the Administrator focuses on area-wide O_3 concentrations at or above 40 ppb and 60 ppb. For area-wide O_3 concentrations at or above 40 ppb, the Administrator notes that revised standards with levels of 70 or 65 ppb are estimated to reduce the number of premature deaths associated with short-term O_3 concentrations by about 10% and almost 50%, respectively, compared to the current standard.[168] In addition, for area-wide concentrations at or above 60 ppb, revised standards are estimated to reduce O_3-associated premature deaths by about 50% to 70% for a standard level of 70 ppb, and by more than 80% for a standard level of 65 ppb.[169] Risk reductions are smaller when total risks are considered (II.C.3.b).

Given all of the above evidence, exposure/risk information, and advice from CASAC, the Administrator proposes to revise the level of the current primary O_3 standard to within the range of 65 to 70 ppb. She concludes that a standard with a level from within this range could reasonably be judged to be requisite to protect public health with an adequate margin of safety, based on her consideration of the evidence and information discussed above. In reaching this conclusion, she particularly notes that a level from anywhere within this range would be below the lowest O_3 exposure concentration shown to result in the

[167] The ISA concludes that there is less certainty in the shape of concentration-response functions for area-wide O_3 concentrations at the lower ends of warm season distributions (*i.e.,* below about 20 to 40 ppb) (U.S. EPA, 2013a, section 2.5.4.4).

[168] For area-wide O_3 concentrations at or above 40 ppb, reductions in estimated premature deaths are disproportionately larger with the 65 ppb standard level than with the 70 ppb standard level. This results from the larger air quality adjustments required to meet the 65 ppb level. Across urban study areas, the additional reductions required to meet 65 ppb result in many fewer days with area-wide O_3 concentrations at or above 40 ppb and, therefore, many fewer O_3-associated deaths for area-wide concentrations at or above 40 ppb (U.S. EPA, 2014a, Figures 7–2 and 7–3).

[169] Though only a relatively small number of days in urban study areas had area-wide O_3 concentrations at or above 60 ppb.

adverse combination of respiratory symptoms and lung function decrements (*i.e.,* 72 ppb), would be expected to maintain ambient O_3 concentrations below those in locations where single-city studies assessed in the ISA have reported statistically significant O_3 health effect associations, and would be expected to result in important reductions in O_3 exposures and health risks, compared to the current standard.

The Administrator notes that the determination of what constitutes an adequate margin of safety is expressly left to the judgment of the EPA Administrator. She further notes that in evaluating how particular standards address the requirement to provide an adequate margin of safety, the Administrator must consider such factors as the nature and severity of the health effects, the size of sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed (I.B, above). Consistent with past practice and long-standing judicial precedent, she takes the need for an adequate margin of safety into account as an integral part of her decision-making on the appropriate level, averaging time, form, and indicator of the standard.[170]

The Administrator notes that the NAAQS are not designed to be zero-risk or background standards, and that the sizeable risk reductions that are estimated in the HREA to be associated with standard levels of 65 or 70 ppb represent substantial improvements in public health for important segments of the population, including at-risk groups such as children and people with asthma. Although any rationale supporting a decision to set a specific level within the range of 65 to 70 ppb would discuss the full body of evidence and information, the Administrator notes that certain aspects of this evidence and information could be particularly important in distinguishing between the appropriateness of a level closer to 65 ppb versus a level closer to 70 ppb.[171]

For example, a level at or near 65 ppb could be judged requisite to protect public health with an adequate margin of safety to the extent the Administrator places greater weight on the importance of: (1) Eliminating almost all exposures of concern (even single occurrences) at or above 70 and 80 ppb, even in worst-case years and locations; (2) almost eliminating the occurrence of two or more exposures of concern at or above 60 ppb; (3) achieving additional reductions in O_3-induced FEV_1 decrements, beyond those achieved with a level of 70 ppb (4) maintaining ambient concentrations below those in locations of single-city studies and more effectively doing so for multicity studies (*i.e.,* more effectively than 70 ppb); and (5) achieving substantial reductions, compared to a standard with a level of 70 ppb, in mortality associated with the upper portion of the distribution of ambient O_3 concentrations, despite uncertainties in risk estimates.

In contrast, a level at or near 70 ppb could be judged requisite to protect public health with an adequate margin of safety to the extent the Administrator places a greater amount of weight (*i.e.,* greater than for 65 ppb) on the importance of: (1) Almost eliminating the occurrence of two or more exposures of concern at or above 70 and 80 ppb, even in the worst-case year and location; (2) substantially reducing, but not eliminating, the occurrence of two or more exposures of concern at or above 60 ppb, noting conclusions regarding increasing uncertainty in adverse effects for the 60 ppb benchmark; (3) reducing, but not eliminating, the occurrence of one or more exposures of concern, noting that not all exposures of concern result in adverse effects; (4) maintaining ambient O_3 concentrations below those in locations of single-city epidemiologic studies, and uncertainties in analyses of air quality in multicity study locations; and (5) recognizing uncertainties in epidemiology-based risk estimates.

In considering CASAC advice on the range of standard levels, the Administrator first notes CASAC's conclusion that there is adequate scientific evidence to consider a range of levels for a primary standard that includes an upper end at 70 ppb. For the reasons discussed above, she agrees with this advice. She also notes that while CASAC concluded that a standard with a level of 70 ppb ''may not meet the statutory requirement to protect public health with an adequate margin of safety'' (Frey, 2014c, p. 8), it further acknowledged that ''the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act'' (Frey, 2014c, p. ii). While she agrees with CASAC that it is appropriate to consider levels below 70 ppb, as reflected in her range of proposed levels from 65 to 70 ppb, for the reasons discussed above she also concludes that a standard level as high as 70 ppb, which CASAC concluded could be supported by the scientific evidence, could reasonably be judged to be requisite to protect public health with an adequate margin of safety.

The Administrator has also considered the appropriateness of standard levels below 65 ppb. In doing so, she notes the conclusions of the PA and the advice of CASAC that it would be appropriate for her to consider standard levels as low as 60 ppb. In particular, she notes that a decision to set the primary O_3 standard level at 60 ppb would place a large amount of weight on the potential public health importance of virtually eliminating even single occurrences of exposures of concern at and above 60 ppb, though controlled human exposure studies have not reported the adverse combination of respiratory symptoms and decrements in lung function following exposures to 60 ppb O_3; on the potential public health importance of further reducing the occurrence of O_3-induced lung function decrements ≥10 and 15%; on analyses of ambient O_3 concentrations in locations of multicity epidemiologic studies, despite uncertainties in linking multicity effect estimates for short-term O_3 with air quality in individual study cities; and on epidemiology-based risk estimates, despite the important uncertainties in those estimates. However, as discussed more fully above, given the uncertainties associated with the adversity of exposures to 60 ppb O_3, particularly single occurrence of such exposures; uncertainties associated with air quality analyses in locations of multicity epidemiologic studies; and uncertainties in epidemiology-based risk estimates, particularly uncertainties in the shape of the concentration-response functions at lower O_3 concentrations and uncertainties associated with the heterogeneity in O_3 effect estimates across locations, the Administrator does not agree that it is appropriate to place significant weight on these factors or to use them to support the appropriateness of standard levels below 65 ppb. Compared to O_3 standard levels from 65 to 70 ppb, the Administrator concludes that the extent to which standard levels below 65 ppb could result in further public health improvements becomes notably less certain. Therefore, she concludes that it

[170] See, *e.g., NRDC* v. *EPA,* 902 F. 2d 962, 973–74 (D.C. Cir. 1990).

[171] Although this discussion refers to supporting rationale for a level of 65 ppb or 70 ppb, the Administrator is proposing the entire range between 65 and 70 ppb. The Administrator notes that although neither the PA nor CASAC reached conclusions or provided advice on a standard set at a specific level between 65 ppb and 70 ppb, there is nothing in either the evidence, exposure/risk information, or CASAC advice that would preclude such a standard level.

is not appropriate to propose standard levels below 65 ppb.[172]

The Administrator acknowledges that her proposed range of 65 to 70 ppb does not include the lower portion of the range supported by CASAC. In reaching the conclusion that this is appropriate, she focuses on CASAC's rationale for levels as low as 60 ppb. In particular, she notes the following CASAC advice (Frey, 2014c, p. 7):

> The CASAC concurs that 60 ppb is an appropriate and justifiable scientifically based lower bound for a revised primary standard. This is based upon findings of adverse effects, including clinically significant lung function decrements and airway inflammation, after exposures to 60 ppb ozone in healthy adults with moderate exertion (Adams 2006; Schelegle et al., 2009; Brown et al., 2008; Kim et al., 2011), with limited evidence of adverse effects below 60 ppb.

In considering this advice, the Administrator notes that CASAC focused on the importance of limiting exposures to O_3 concentrations as low as 60 ppb. As discussed above, the Administrator agrees with this advice. In particular, she notes that standards within the proposed range of 65 to 70 ppb would be expected to substantially limit the occurrence of exposures of concern to O_3 concentrations at or above 60 ppb, particularly the occurrence of two or more exposures.[173] When she further considers that not all exposures of concern lead to adverse effects, and that the NAAQS are not meant to be zero-risk or background standards, the Administrator judges that alternative standard levels below 65 ppb are not needed to further reduce such exposures. Therefore, the Administrator's initial conclusion is that standard levels below 65 ppb would be more than requisite to protect public health with an adequate margin of safety.

In reaching this initial conclusion, the Administrator acknowledges that alternative approaches to viewing the available scientific evidence and exposure/risk information, and to viewing the uncertainties inherent in that evidence and information, could lead one to reach a different conclusion. In particular, as noted above, she recognizes that levels as low as 60 ppb could potentially be supported, to the extent substantial weight is placed on the public health importance of estimates of one or more occurrences of exposures of concern at or above 60 ppb and O_3-induced lung function decrements ≥10%; analyses of ambient O_3 concentrations in locations of multicity epidemiologic studies; and epidemiology-based estimates of total risk. This approach would also place a large amount of weight on the possibility that at-risk groups would experience adverse effects at lower levels than the benchmarks derived from clinical studies conducted using healthy adult subjects, despite the fact that these studies have not reported a statistically significant increase in respiratory symptoms, combined with lung function decrements, following exposures to 60 ppb.[174] Such an approach to viewing the evidence and exposure/risk information would place very little weight on the uncertainties in these estimates and analyses. In some cases, elements of this approach have been supported by public commenters, leading some commenters to recommend setting the level of the primary O_3 standard at least as low as 60 ppb. In recognition of such an alternative approach to viewing the evidence and information, in addition to proposing to set the level of the O_3 standard from 65 to 70 ppb, the Administrator solicits comment on alternative standard levels below 65 ppb, and as low as 60 ppb. In doing so, the Administrator reiterates that the CAA does not require the establishment of a primary NAAQS at a zero-risk level or at background concentration levels, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety (I.A).

F. Proposed Decision on the Primary Standard

For the reasons discussed above, and taking into account information and assessments presented in the 2013 ISA, 2014 HREA and integration of this information and assessments into staff conclusions in the 2014 PA, the advice and recommendations of CASAC, and public comments received during the development of these documents, the Administrator proposes to retain the current indicator, averaging time and form of the primary O_3 standard, and to set a new level for the 8-hour primary O_3 standard. Specifically, the Administrator proposes to set the level of the 8-hour primary O_3 standard to within the range of 65 to 70 ppb. The proposed 8-hour primary standard would be met at an ambient air monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is less than or equal to the level of the revised standard that is promulgated. Thus, the Administrator proposes to set a standard with a level within this range. For the reasons discussed above, the Administrator also solicits comment on setting the level of the primary O_3 standard below 65 ppb, and as low as 60 ppb.

III. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. The AQI has been in use since its inception in 1999 (64 FR 42530). It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). It is designed to tell individual members of the public how clean or unhealthy their air is, whether health effects might be a concern, and, if so, measures individuals can take to reduce their exposure to air pollution. The AQI focuses on health effects individuals may experience within a few hours or days after breathing unhealthy air. The AQI establishes a nationally uniform system of indexing pollution concentrations for O_3, carbon monoxide, nitrogen dioxide, particulate matter and sulfur dioxide. The AQI converts pollutant concentrations in a community's air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution concentrations in a particular location are characterized as good (0–50), moderate (51–100), unhealthy for sensitive groups (101–150), unhealthy (151–200), very unhealthy (201–300), or hazardous (301–500). The AQI index value of 100 typically corresponds to the level of the short-term NAAQS for each pollutant. For the O_3 NAAQS, an 8-hour average concentration of 75 ppb corresponds to an AQI value of 100. An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (*i.e.,* unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day; an AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (*i.e.,* moderate or good). An additional consideration in

[172] Although, as discussed below, she solicits comment on standard levels as low as 60 ppb.

[173] In fact, as noted above (Table 4), a standard with a level of 70 ppb would be expected to limit multiple occurrences of exposures of concern at or above the 60 ppb benchmark to as low as 0.5% in urban case study areas (and as low as 0% for a standard with a level of 65 ppb).

[174] More specifically, as discussed above, respiratory symptoms have been evaluated following 6.6-hour exposures to average O_3 concentrations of 60 ppb (Adams, 2006; Kim et al., 2011) and 63 ppb (Schelegle et al., 2009). None of these studies reported a statistically significant increase in respiratory symptoms, compared to filtered air controls.

selecting breakpoints is for each category to span at least a 15 ppb range to allow for more accurate forecasting. Decisions about the pollutant concentrations at which to set the various AQI breakpoints, that delineate the various AQI categories, draw directly from the underlying health information that supports the NAAQS review.

The Agency recognizes the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS. Therefore EPA is proposing conforming changes to the AQI, in connection with the Agency's proposed decision on revisions to the O_3 NAAQS if revisions to the primary standard are promulgated. These conforming changes would include setting the 100 level of the AQI at the same level as the revised primary O_3 NAAQS and also making adjustments based on health information from this NAAQS review to AQI breakpoints at the lower end of each range (*i.e.,* AQI values of 50, 150, 200 and 300). The EPA does not propose to change the level at the top of the index (*i.e.,* AQI value of 500) that typically is set equal to the Significant Harm Level (40 CFR 51.16), which would apply to state contingency plans.

The EPA is proposing to revise the AQI for O_3 by setting an AQI value of 100 equal to the level of the revised O_3 standard (65–70 ppb). The EPA is also proposing to revise the following breakpoints: An AQI value of 50 to within a range from 49–54 ppb; an AQI value of 150 to 85 ppb; an AQI value of 200 to 105 ppb, and an AQI value of 300 to 200 ppb. All these levels are averaged over 8 hours. The EPA is proposing to set an AQI value of 50, the breakpoint between the good and moderate categories, at 15 ppb below the value of the proposed standard, *i.e.* to within a range from 49 to 54 ppb. The EPA is taking comment on what level within this range to select, recognizing that there is no health message for either at-risk or healthy populations in the good category. Thus, the level selected should be below the lowest concentration (*i.e.,* 60 ppb) that has been shown in controlled human exposure studies of healthy adults [175] to cause moderate lung function decrements (*i.e.,* FEV_1 decrements ≥10%, which could be adverse to people with lung disease), large lung function decrements (*i.e.,* FEV_1 decrements ≥20%) in a small proportion of people, and airway inflammation.[176] The EPA is proposing to set an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, at 85 ppb. At this level, controlled human exposure studies of healthy adults indicate that up to 25% of exposed people are likely to have moderate lung function decrements (*i.e.,* 25% have FEV_1 decrements ≥10%; 12% have FEV_1 decrements ≥15%) and up to 7% are likely to have large lung function decrements (*i.e.,* FEV_1 decrements ≥20%) (McDonnell et al., 2012; Figure 7). Large lung function decrements would likely interfere with normal activity for many healthy people. For people with lung disease, large lung function decrements would likely interfere with normal activity for most people and would increase the likelihood that they would seek medical treatment (72 FR 37850, July 11, 2007). The EPA is proposing to set an AQI value of 200, the breakpoint between the unhealthy and very unhealthy categories, at 105 ppb. At this level, controlled human exposure studies of healthy adults indicate that up to 38% of exposed people are likely to have moderate lung function decrements (*i.e.,* 38% have FEV_1 decrements ≥10%; 22% have FEV_1 decrements ≥15%) and up to 13% are likely to have large lung function decrements (*i.e.,* FEV_1 decrements ≥20%). The EPA is proposing to set an AQI value of 300, the breakpoint between the very unhealthy and hazardous categories, at 200 ppb. At this level, controlled human exposure studies of healthy adults indicate that up to 25% of exposed individuals are likely to have large lung function decrements (*i.e.,* FEV_1 decrements ≥20%), which would interfere with daily activities for many of them. Large lung function decrements would interfere with daily activities for most people with lung disease, and likely cause them to seek medical attention.

TABLE 6—PROPOSED AQI BREAKPOINTS

AQI category	Index values	Existing breakpoints (ppb, 8-hour average)	Proposed breakpoints (ppb, 8-hour average)
Good	0–50	0–59	0–(49 to 54).
Moderate	51–100	60–75	(50 to 55)–(65 to 70).
Unhealthy for Sensitive Groups	101–150	76–95	(66 to 71)–85.
Unhealthy	151–200	96–115	86–105.
Very Unhealthy	201–300	116–374	106–200.
Hazardous	301–400	375–	201–.
	401–500		

EPA believes that the proposed breakpoints reflect an appropriate balance between reflecting the health evidence that is the basis for the proposed primary O_3 standard and providing category ranges that are large enough to be forecasted accurately, so that the new AQI for O_3 can be implemented more easily in the public forum for which the AQI ultimately exists. However, the EPA recognizes that some have expressed alternative approaches to viewing the evidence and information and solicits comment on these proposed revisions to the AQI.

With respect to reporting requirements (40 CFR part 58, § 58.50), EPA proposes to revise 40 CFR part 58, § 58.50 (c) to require the AQI reporting requirements to be based on the latest available census figures, rather than the most recent decennial U.S. census. This change is consistent with our current practice of using the latest population figures to make monitoring requirements more responsive to changes in population.

[175] Effects would likely be greater in people with asthma.

[176] Exposures to 50 ppb have not been evaluated experimentally, but are estimated to potentially affect only a small proportion of healthy adults and with only a half to a third of the moderate to large lung function decrements observed at 60 ppb (McDonnell et al., 2012; Figure 7).

IV. Rationale for Proposed Decision on the Secondary Standard

This section presents the rationale for the Administrator's proposed decisions regarding the need to revise the current secondary O_3 NAAQS and the appropriate revisions to the standard, including her proposed decisions that the current secondary standard is not requisite to protect public welfare and should be revised to provide additional public welfare protection. Based on her consideration of the full body of welfare effects evidence and related analyses, the Administrator proposes to conclude that ambient O_3 concentrations in terms of a W126 index value, averaged across three consecutive years, within the range from 13 ppm-hrs to 17 ppm-hrs would provide the requisite protection against known or anticipated adverse effects to the public welfare. In considering policy options for achieving that level of air quality, the Administrator has further considered the full body of information, including air quality analyses that relate ambient O_3 concentrations in terms of a three-year average W–126-based metric and in terms of the form and averaging time for the current standard. Based on this consideration, the Administrator proposes to revise the level of the current secondary standard to within the range of 0.065 to 0.070 ppm to achieve the appropriate air quality.

As discussed more fully below, this proposal is based on a thorough review, in the ISA, of the latest scientific information on O_3-induced environmental effects. This proposed decision also takes into account: (1) Staff assessments in the PA of the most policy-relevant information in the ISA and WREA analyses of air quality, exposure, and ecological risks and associated ecosystem services; (2) CASAC advice and recommendations; and, (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

This proposed decision draws on the ISA's integrative synthesis of the entire body of evidence, published through July 2011, on environmental effects associated with the presence of O_3 and related photochemical oxidants in the ambient air. As summarized in section IV.B below, this body of evidence addresses the range of environmental responses associated with exposure to ambient levels of O_3 (U.S. EPA, 2013a, ISA chapters 9–10), and includes more than four hundred new studies that build on the extensive evidence base from the last review. This rationale also draws upon the results of quantitative exposure and risk assessments, summarized in section IV.C below. Section IV.D presents the Administrator's proposed decisions on the adequacy of the current secondary standard (section IV.D.3) drawing on both evidence-based and exposure/risk-based considerations in the PA (section IV.D.1) and advice from CASAC (section IV.D.2). Proposed conclusions on alternative standards are summarized in section IV.E.

A. Approach

In evaluating whether it is appropriate to retain or revise the current secondary O_3 standard, the Administrator adopts an approach in this review that builds upon the general approach used in the 2008 review [177] and reflects the broader body of scientific evidence now available, updated exposure/risk information, advances in O_3 air quality modeling, and air monitoring information. This review of the standard also considers the July 2013 remand of the secondary standard by the U.S. Court of Appeals for the D.C. Circuit, such that the proposed decision described herein incorporates the EPA's response to this remand.

The Administrator's decisions in the 2008 review were based on an integration of information on welfare effects associated with exposure to O_3, judgments on the adversity and public welfare significance of key effects, and judgments as to what standard would be requisite to protect public welfare. These considerations were informed by air quality and related analyses, quantitative exposure and risk assessments, and qualitative assessment of impacts that could not be quantified. As a result of the 2008 review, the Administrator concluded the then-current secondary standard did not provide the requisite public welfare protection and it was revised. The current secondary standard is 75 ppb based on the annual fourth-highest daily maximum 8-hour average concentration, averaged over three consecutive years, which is identical to the current primary standard. In 2008, the Administrator considered the then-available monitoring data with regard to relationships between the revised primary standard and degree of protection of public welfare from cumulative seasonal O_3 exposures, expressed in terms of the W126 exposure index (described in section IV.B.1 below), and decided to revise the secondary standard to be equal to the revised primary standard (73 FR 16499–16500, March 27, 2008). In remanding the 2008 decision on the secondary standard back to the EPA (described in section I.C above), the U.S. Court of Appeals for the D.C. Circuit determined that EPA did not specify what level of air quality was requisite to protect public welfare from adverse public welfare effects or explain why any such level would be requisite. *Mississippi,* 744 F.3d at 272–73.

In addition to reviewing the most recent scientific information as required by the CAA, this rulemaking responds to the remand and fully explains the Administrator's proposed conclusions as to the level of air quality requisite to protect public welfare from known or anticipated effects. Our general approach in considering the scientific information available in this review involves consideration of the integrative synthesis of the entire body of available scientific evidence in the ISA (U.S. EPA, 2013a), including information on biologically relevant exposure indices, exposure/risk and air quality modeling analyses presented in the WREA (U.S. EPA, 2014b), staff analyses in the PA; advice and recommendations from CASAC (Frey, 2014b, c), and public comments. We note that in drawing conclusions on the secondary standard, the final decision to retain or revise the standard is a public welfare policy judgment to be made by the Administrator. The Administrator's final decision will draw upon the available scientific evidence for O_3-attributable welfare effects and on analyses of exposures and public welfare risks based on impacts to vegetation, ecosystems and their associated services, as well as judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. Such judgments in the context of this review include: The weight to place on the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O_3 exposures; the weight to give associated uncertainties, including those related to the variability in occurrence of such effects in areas of the U.S., especially areas of particular public welfare significance; and, judgments on the extent to which such effects in such areas may be considered adverse to public welfare.

As provided in the CAA, section 109(b)(2), the secondary standard is to ''specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . .

[177] The 2008 revision of the O_3 secondary standard, the proposed reconsideration of the 2008 decision, and the 2013 court decision on the 2008 revision of the secondary standard are summarized in section I.C above.

is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.'' Effects on welfare include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being'' (CAA section 302(h)). As recognized in the last review, the secondary standard is not meant to protect against all known or anticipated O_3-related effects, but rather those that are judged to be adverse to the public welfare (73 FR 16496, March 27, 2008). Thus, the level of protection from known or anticipated adverse effects to public welfare that is requisite for the secondary standard is a public welfare policy judgment to be made by the Administrator. In the current review, the Administrator's judgment is informed by conclusions drawn with regard to adversity of effects to public welfare in decisions on secondary O_3 standards in past reviews.

In the 2008 decision, the Administrator concluded that the degree to which O_3 effects on vegetation should be considered to be adverse to the public welfare depends on the intended use of the vegetation and the significance of the vegetation to the public welfare, and also applied this concept beyond the species level to the ecosystem level (73 FR 16496, March 27, 2008). In so doing, the Administrator took note of ''a number of actions taken by Congress to establish public lands that are set aside for specific uses that are intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation and wildlife within such areas, and to leave them unimpaired for the enjoyment of future generations'' (73 FR 16496, March 27, 2008). The notice for the 2008 decision further noted that [s]uch public lands that are protected areas of national interest include national parks and forests, wildlife refuges, and wilderness areas'' (73 FR 16496, March 27, 2008).[178] [179] The Administrator additionally recognized that ''States, Tribes and public interest groups also set aside areas that are intended to provide similar benefits to the public welfare, for residents on State and Tribal lands, as well as for visitors to those areas'' (73 FR 16496, March 27, 2008). The Administrator took note of the ''clear public interest in and value of maintaining these areas in a condition that does not impair their intended use and the fact that many of these lands contain O_3-sensitive species'' (73 FR 16496, March 27, 2008). Similarly, in judgments of adversity to public welfare in the 2010 proposed reconsideration, the Administrator proposed to place the highest priority and significance on vegetation and ecosystem effects to sensitive species that are known to or are likely to occur in federally protected areas such as national parks and other Class I areas,[180] or on lands set aside by states, tribes and public interest groups to provide similar benefits to the public welfare (75 FR 3023–24, January 19, 2010).

In the current review, our consideration of the scientific evidence for effects on vegetation is based fundamentally on using information from controlled chamber studies, free air methodologies, and field-based observational, survey and gradient studies. Such evidence, discussed below, informs consideration of welfare endpoints and at-risk species and ecosystems on which to focus the current review, and consideration of the ambient O_3 conditions under which various welfare effects are known or anticipated to occur. As in past reviews, we recognize that the available evidence has not provided identification of a threshold in exposure or ambient O_3 concentrations below which it can be concluded with confidence that O_3-attributable effects on vegetation do not occur, when considering the broad range of O_3-sensitive plant species growing within the U.S and the array of effects. This is due in part to the fact that research shows that there is variability in sensitivity between and within species and that numerous factors, *i.e.,* chemical, physical, biological, and genetic, can influence the direction and magnitude of the studied effect (U.S. EPA, 2013a, section 9.4.8). In the absence of evidence for a discernible threshold, the general approach to considering the available O_3 welfare effects evidence involves characterizing the confidence in conclusions regarding O_3-attributable vegetation effects over the ranges of cumulative seasonal O_3 exposure values evaluated in chamber studies and in field studies in areas where O_3-sensitive vegetation are known to occur, as well as characterizing the extent to which these effects can be considered adverse at the plant level and beyond. With this approach, we consider the evidence for O_3 affecting other ecosystem components (such as soils, water, and wildlife) and their associated goods and services, through its effects on vegetation, as well as the associated uncertainties.

Our general approach further recognizes the complexity of judgments to be made regarding the identification of particular vegetation effects as welfare effects and regarding the point that known or anticipated vegetation-related effects become adverse to the public welfare. For example, in addition to the magnitude of the ambient concentrations, the species present, their sensitivity to O_3, and their public welfare importance are also essential considerations in drawing conclusions regarding the significance of public welfare impact. Taking this into account, we recognize the existence of a continuum from relatively higher ambient O_3 concentrations and conditions, in areas with sensitive species and public welfare significance, for which there might be general agreement that effects on public welfare are likely to occur, through lower concentrations at which the degree to which public welfare might be expected to be affected becomes increasingly uncertain.

The evidence base for this review, summarized in section IV.B below, includes quantitative information across a broad array of vegetation effects (*e.g.,* growth impairment during seedling, sapling and mature tree growth stages, visible foliar injury, and yield loss in annual crops) and across a diverse set of exposure methods from laboratory and field studies. While considering the full breadth of information available, we place greater weight on U.S. studies due to the often species-, site-, and climate-

[178] For example, the National Park Service Organic Act of 1916 established the National Park Service (NPS) and, in describing the role of the NPS with regard to ''Federal areas known as national parks, monuments, and reservations'', stated that the ''fundamental purpose'' for these Federal areas ''is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations.'' 16 U.S.C. 1.

[179] As a second example, the Wilderness Act of 1964 defines designated ''wilderness areas'' in part as areas ''protected and managed so as to preserve [their] natural conditions'' and requires that these areas ''shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use and enjoyment as wilderness, and so as to provide for the protection of these areas, [and] the preservation of their wilderness character . . .'' 16 U.S.C. 1131 (a).

[180] As defined by section 162 of the CAA, Class I areas include all international parks, national wilderness areas which exceed 5,000 acres in size, national memorial parks which exceed 5,000 acres in size, and national parks which exceed six thousand acres in size, provided the park or wilderness area was in existence on August 7, 1977, as well as other areas designated as Class I consistent with that section of the Act. The current Class I areas are specified at 40 CFR part 81.

specific nature of O_3-related vegetation responses, and particularly emphasize those studies that include O_3 exposures that fall within the range of those likely to occur in the ambient air. We additionally recognize differences across different study types in what information they provide (U.S. EPA, 2013a, section 9.2.6). For example, because conditions can be controlled in laboratory studies, responses in such studies may be less variable and smaller differences may be easier to detect. However, the controlled conditions may limit the range of responses or incompletely reflect pollutant bioavailability, so they may not reflect responses that would occur in the natural environment. Alternatively, field data can provide important information for assessments of multiple stressors or where site-specific factors significantly influence exposure. They are also often useful for analyses of larger geographic scales and higher levels of biological organization. However, depending on the type of field study, many field study conditions may not be controlled, which can make variability higher and differences harder to detect. In some field studies (*e.g.,* gradient studies), the presence of confounding factors can also make it difficult to attribute observed effects to specific stressors.

In developing quantitative exposure and risk assessments for this review, summarized in section IV.C below, we have placed greatest emphasis on studies that have evaluated plant response over multiple exposure levels and developed exposure-response (E–R) relationships that allow the estimation of plant responses over the range of O_3 exposures pertinent to judgments on the current and potential alternative standards. In considering the information from these assessments, we focus particularly on the quantitative risks related to three types of O_3 effects on vegetation and associated ecosystem services: visible foliar injury, biomass loss in trees, and crop yield loss. These risks were assessed in a range of analyses primarily involving national-scale air quality scenarios developed using model adjustments and interpolation methods. We consider particularly the national scale assessments for these scenarios, while recognizing the uncertainties with regard to the conditions they represent.

With regard to the appropriate characterization of exposures associated with ambient O_3 concentrations, as in the 2008 and 1997 reviews, we continue to recognize the relevance of cumulative, seasonal, concentration-weighted exposures for assessing vegetation effects. More specifically, in the 2008 review, the EPA concluded and the CASAC agreed that the W126 cumulative exposure metric was the most appropriate to use to evaluate both the adequacy of the current secondary standard and the appropriateness of any potential revisions. As discussed in section IV.B.1 below, the information available in this review continues to support the use of such a metric and it is used in considering potential public welfare impacts in the sections below.

B. Welfare Effects Information

1. Nature of Effects and Biologically Relevant Exposure Metric

This section describes the nature of O_3-induced welfare effects, including the nature of the exposures that drive the biological and ecological responses (U.S. EPA, 2013a, chapter 9).

Ozone's phytotoxic effects were first identified on grape leaves in a study published in 1958 (Richards et al., 1958). In the almost fifty years that have followed, extensive research has been conducted both in and outside of the U.S. to examine the impacts of O_3 on plants and their associated ecosystems, since ''of the phytotoxic compounds commonly found in the ambient air, O_3 is the most prevalent, impairing crop production and injuring native vegetation and ecosystems more than any other air pollutant'' (U.S. EPA, 1989, 1996a). As was established in prior reviews, O_3 can interfere with carbon gain (photosynthesis) and allocation of carbon within the plant. As a result of decreased carbohydrate availability, fewer carbohydrates are available for plant growth, reproduction, and/or yield. For seed-bearing plants, these reproductive effects will culminate in reduced seed production or yield (U.S. EPA, 1996a, pp. 5–28 and 5–29). Recent studies, assessed in the ISA, together with this longstanding and well-established literature on O_3-related vegetation effects, further contribute to the coherence and consistency of the vegetation effects evidence. As described in the ISA, a variety of factors in natural environments can either mitigate or exacerbate predicted O_3-plant interactions and are recognized sources of uncertainty and variability. These include: (1) Multiple genetically influenced determinants of O_3 sensitivity; (2) changing sensitivity to O_3 across vegetative growth stages; (3) co-occurring stressors and/or modifying environmental factors (U.S. EPA, 2013a, section 9.4.8).

Among the studies of vegetation effects, the ISA recognizes controlled chamber studies as the best method for isolating or characterizing the role of O_3 in inducing the observed plant effects, and in assessing plant response to O_3 at the finer scales (U.S. EPA, 2013a, sections 9.2 and 9.3). Recent controlled studies have focused on a variety of plant responses to O_3 including the underlying mechanisms governing such responses. These mechanisms include: (1) Reduced carbon dioxide uptake due to stomatal closure (U.S. EPA, 2013a, section 9.3.2.1); (2) the upregulation of genes associated with plant defense, signaling, hormone synthesis and secondary metabolism (U.S. EPA, 2013a, section 9.3.3.2); (3) the down regulation of genes related to photosynthesis and general metabolism (U.S. EPA, 2013a, section 9.3.3.2); (4) the loss of carbon assimilation capacity due to declines in the quantity and activity of key proteins and enzymes (U.S. EPA, 2013a, section 9.3.5.1); and (5) the negative impacts on the efficiency of the photosynthetic light reactions (U.S. EPA, 2013a, section 9.3.5.1). As described in the ISA, these new studies ''have increased knowledge of the molecular, biochemical and cellular mechanisms occurring in plants in response to O_3'', adding ''to the understanding of the basic biology of how plants are affected by oxidative stress . . .'' (U.S. EPA, 2013a, p. 9–11). The ISA further concludes that controlled studies ''have clearly shown that exposure to O_3 is causally linked to visible foliar injury, decreased photosynthesis, changes in reproduction, and decreased growth'' in many species of vegetation (U.S. EPA, 2013a, p. 1–15).

Such effects at the plant scale can also be linked to an array of effects at larger spatial scales. For example, recent field studies at larger spatial scales, together with previously available evidence, support the controlled exposure study results and indicate that ''ambient O_3 exposures can affect ecosystem productivity, crop yield, water cycling, and ecosystem community composition'' (U.S. EPA, 2013a, p. 1–15; Chapter 9, section 9.4). The current body of O_3 welfare effects evidence confirms the conclusions reached in the last review on the nature of O_3-induced welfare effects and is summarized in the ISA as follows (U.S. EPA, 2013a, p. 1–8).

> The welfare effects of O_3 can be observed across spatial scales, starting at the subcellular and cellular level, then the whole plant and finally, ecosystem-level processes. Ozone effects at small spatial scales, such as the leaf of an individual plant, can result in effects along a continuum of larger spatial scales. These effects include altered rates of leaf gas exchange, growth, and reproduction at the individual plant level, and can result

in broad changes in ecosystems, such as productivity, carbon storage, water cycling, nutrient cycling, and community composition.

Based on its assessment of this extensive body of science, the ISA determines that, with respect to vegetation and ecosystems, a causal relationship exists between exposure to O_3 in ambient air and visible foliar injury effects on vegetation, reduced vegetation growth, reduced productivity in terrestrial ecosystems, reduced yield and quality of agricultural crops and alteration of below-ground biogeochemical cycles [181] (U.S. EPA, 2013a, Table 1–2). In consideration of the evidence of O_3 exposure and alterations in stomatal performance, ''which may affect plant and stand transpiration and therefore possibly affecting hydrological cycling,'' the ISA concludes that ''[a]lthough the direction of the response differed among studies,'' the evidence is sufficient to conclude a likely causal relationship between O_3 exposure and the alteration of ecosystem water cycling (U.S. EPA, 2013a, section 2.6.3). The ISA also concludes that the evidence is sufficient to conclude a likely causal relationship between O_3 exposure and the alteration of community composition of some terrestrial ecosystems (U.S. EPA, 2013a, section 2.6.5). Related to the effects on vegetation growth, productivity and, to some extent, below-ground biogeochemical cycles, the ISA additionally determines that a likely causal relationship exists between exposures to O_3 in ambient air and reduced carbon sequestration (also termed carbon storage) [182] in terrestrial ecosystems (U.S. EPA, 2013a, p. 1–10 and section 2.6.2). Modeling studies available in this review consistently found negative impacts of O_3 on carbon sequestration, although the severity of impact was influenced by ''multiple interactions of biological and environmental factors'' (U.S. EPA, 2013a, p. 2–39).

The ISA notes that ''[t]he suppression of ecosystem [carbon] sinks results in more [carbon dioxide] accumulation in the atmosphere'' and that a recent study has suggested that ''the indirect radiative forcing caused by O_3 exposure through lowering the ecosystem [carbon] sink could have an even greater impact on global warming than the direct radiative forcing of O_3'' (U.S. EPA, 2013a, p. 2–39). With regard to direct radiative forcing, however, the ISA makes a stronger causality conclusion that the evidence supports a causal relationship between changes in tropospheric O_3 concentrations and radiative forcing [183] (U.S. EPA, 2013a, section 2.7.1). There are, however, ''large uncertainties in the magnitude of the radiative forcing estimate attributed to tropospheric O_3, making the impact of tropospheric O_3 on climate more uncertain than the effect of the longer-lived greenhouse gases'' (U.S. EPA, 2013a, p. 2–47). In this regard, the ISA observes that ''radiative forcing does not take into account the climate feedbacks that could amplify or dampen the actual surface temperature response,'' that ''[q]uantifying the change in surface temperature requires a complex climate simulation in which all important feedbacks and interactions are accounted for'' and that ''[t]he modeled surface temperature response to a given radiative forcing is highly uncertain and can vary greatly among models and from region to region within the same model'' (U.S. EPA, 2013a, p. 2–47). Even with these uncertainties, the ISA notes that ''global climate models indicate that tropospheric O_3 has contributed to observed changes in global mean and regional surface temperatures'' and as a result of such evidence presented in climate modeling studies, concludes that there is likely to be a causal relationship between changes in tropospheric O_3 concentrations and effects on climate (U.S. EPA, 2013a, p. 2–47). The ISA additionally notes, however, that ''[i]mportant uncertainties remain regarding the effect of tropospheric O_3 on future climate change'' (U.S. EPA, 2013a, p. 10–31).

Given the strong evidence base, and findings of causal or likely causal relationships with O_3 in ambient air, including the quantitative assessments of relationships between O_3 exposure and occurrence and magnitude of effects, we give a primary focus to three main areas of effects. The three main areas, for which the evidence is summarized in more detail below, are: 1) impacts on tree growth, productivity and carbon storage (section IV.B.1.b); 2) crop yield loss (section IV.B.1.c); and 3) visible foliar injury (section IV.B.1.a). Consideration of these three areas includes, as appropriate, consideration of evidence of associated effects at larger scales, including ecosystems, and on associated ecosystem services.

With regard to biologically based indices of exposure pertinent to O_3 effects on vegetation, the ISA states the following (U.S. EPA, 2013a, p. 2–44).

> The main conclusions from the 1996 and 2006 O_3 AQCDs [Air Quality Criteria Documents] regarding indices based on ambient exposure remain valid. These key conclusions can be restated as follows: ozone effects in plants are cumulative; higher O_3 concentrations appear to be more important than lower concentrations in eliciting a response; plant sensitivity to O_3 varies with time of day and plant development stage; [and] quantifying exposure with indices that cumulate hourly O_3 concentrations and preferentially weight the higher concentrations improves the explanatory power of exposure/response models for growth and yield, over using indices based on mean and peak exposure values.

The long-standing body of available evidence upon which these conclusions are based provides a wealth of information on aspects of O_3 exposure that are important in influencing plant response. Specifically, a variety of ''factors with known or suspected bearing on the exposure-response relationship, including concentration, time of day, respite time, frequency of peak occurrence, plant phenology, predisposition, etc.,'' have been identified (U.S. EPA, 2013a, section 9.5.2). In addition, the importance of the duration of the exposure and the relatively greater importance of higher concentrations over lower concentrations in determining plant response to O_3 have been consistently well documented (U.S. EPA, 2013a, section 9.5.3). Much of this evidence was assessed in the 1996 AQCD (U.S. EPA, 1996a), while more recent work substantiating this evidence is assessed in the subsequent 2006 AQCD and 2013 ISA.

Understanding of the biological basis for plant response to O_3 exposure led to the development of a large number of ''mathematical approaches for summarizing ambient air quality information in biologically meaningful forms for O_3 vegetation effects assessment purposes'' (U.S. EPA, 2013a, section 9.5.3), including those that cumulate exposures over some specified period while weighting higher concentrations more than lower (U.S. EPA, 2013a, section 9.5.2). As with any summary statistic, these exposure indices retain information on some, but not all, characteristics of the original observations. The 1996 AQCD contained an extensive review of the published

[181] Based on studies focused on O_3-associated alterations in quality and quantity of carbon input to soil, microbial community composition, and carbon and nutrient cycling, the ISA concludes that the evidence is sufficient ''to infer that there is a causal relationship between O_3 exposure and the alteration of below-ground biogeochemical cycles'' (U.S. EPA, 2013a, pp. 2–41 to 2–42).

[182] The terms sequestration and storage are used somewhat interchangeably in the ISA and other documents in this review.

[183] Radiative forcing by a greenhouse gas or aerosol is a metric used to quantify the change in balance between radiation coming into and going out of the atmosphere caused by the presence of that substance. For example, a reduction in outgoing infrared radiation has been associated with O_3 by satellite data (U.S. EPA, 2013a, p. 2–47).

literature on different types of exposure-response metrics, including comparisons between metrics, from which the 1996 Staff Paper built its assessment of forms appropriate to consider in the context of the secondary NAAQS review. The result of these assessments was a decision by the EPA to focus on cumulative, concentration-weighted indices, which were recognized as the most appropriate biologically based metrics to consider in this context, with attention given primarily to two cumulative, concentration-weighted index forms: SUM06 and W126.[184]

In both the 1997 and 2008 reviews, the EPA concluded that the risk to vegetation comes primarily from cumulative exposures to O_3 over a season or seasons [185] and focused on metrics intended to characterize such exposures: SUM06 (61 FR 65716, December 13, 1996) and W126 (72 FR 37818, July 11, 2007) in the 1997 and 2008 reviews, respectively. Although in both reviews the policy decision was made to set the secondary standard to be identical to a revised primary standard (with an 8-hour averaging time), the Administrator, in both cases, also concluded, consistent with CASAC advice, that a cumulative, seasonal index was the most biologically relevant way to relate exposure to plant growth response (62 FR 38856, July 18, 1997; 73 FR 16436, March 27, 2008; 75 FR 2938, January 19, 2010). This approach for characterizing O_3 exposure concentrations that are biologically relevant with regard to potential vegetation effects received strong support from CASAC in the last review and again in this review, including strong support for use of such a metric as the form for the secondary standard (Henderson, 2006, 2008; Samet, 2010; Frey, 2014c).

An alternative to using ambient exposure durations and concentrations to predict plant response has been developed in recent years, primarily in Europe, *i.e.,* flux models. While ''some researchers have claimed that using flux models can be used {*sic*} to better predict vegetation responses to O_3 than exposure-based approaches'' because flux models estimate the ambient O_3 concentration that actually enters the leaf (*i.e.,* flux or deposition) (U.S. EPA, 2013a, p. 9–114), it is important to note that ''[f]lux calculations are data intensive and must be carefully implemented'' (U.S. EPA, 2013a, p. 9–114). Further, the ISA states, ''[t]his uptake-based approach to quantify the vegetation impact of O_3 requires inclusion of those factors that control the diurnal and seasonal O_3 flux to vegetation (*e.g.,* climate patterns, species and/or vegetation-type factors and site-specific factors)'' (U.S. EPA, 2013a, p. 9–114). In addition to these data requirements, each species has different amounts of internal detoxification potential that may protect species to differing degrees. The lack of detailed species- and site-specific data required for flux modeling in the U.S. and the lack of understanding of detoxification processes have continued to make this technique less viable for use in vulnerability and risk assessments at the national scale in the U.S. (U.S. EPA, 2013a, section 9.5.4).

Therefore, consistent with the ISA conclusions regarding the appropriateness of considering cumulative exposure indices that preferentially weight higher concentrations over lower for predicting O_3 effects of concern based on the long-established conclusions and long-standing supporting evidence described above, and in light of continued CASAC support, we continue to focus on cumulative concentration-weighted indices as the most biologically relevant metrics for consideration of O_3 exposures eliciting vegetation-related effects. Such a metric has an ''explanatory power'' that is improved ''over using indices based on mean and peak exposure values'' (U.S. EPA, 2013a, section 2.6.6.1, p. 2–44). In this review as in the last review, we use the W126 cumulative, seasonal metric (U.S. EPA, 2013a, sections 2.6.6.1 and 9.5.2) for consideration of the effects evidence and in the exposure and risk analyses in the WREA.

The subsections below summarize key aspects of the welfare effects information for O_3-elicited visible foliar injury (section IV.B.1.a), effects on forest tree growth, productivity and carbon storage (section IV.B.1.b) and reductions in crop yield (section IV.B.1.c), as well as associated effects.

a. Visible Foliar Injury

Visible foliar injury resulting from exposure to O_3 has been well characterized and documented over several decades of research on many tree, shrub, herbaceous, and crop species (U.S. EPA, 2013a, p. 1–10; U.S. EPA, 2006a, 1996a, 1986, 1978). Additionally, O_3-induced visible foliar injury symptoms on certain plant species, such as black cherry, yellow-poplar and common milkweed, are considered diagnostic of exposure to O_3 based on the consistent association established with experimental evidence (U.S. EPA, 2013a, p. 1–10). The significance of O_3 injury at the leaf and whole plant levels depends on an array of factors, and therefore, it is difficult to quantitatively relate visible foliar injury symptoms to vegetation effects such as individual tree growth, or effects at population or ecosystem levels (U.S. EPA, 2013a, p. 9–39). The ISA notes that visible foliar injury ''is not always a reliable indicator of other negative effects on vegetation'' (U.S. EPA, 2013a, p. 9–39). Factors that influence the significance to the leaf and whole plant include the amount of total leaf area affected, age of plant, size, developmental stage, and degree of functional redundancy among the existing leaf area (U.S. EPA, 2013a, section 9.4.2). Visible foliar injury by itself is an indication of phytotoxicity due to O_3 exposure, which occurs only when sensitive plants are exposed to elevated O_3 concentrations in a predisposing environment, a major aspect of which is the lack of drought conditions during the year such injury is assessed (U.S. EPA, 2013a, section 9.4.2).

Recent research is consistent with previous conclusions and that O_3-induced visible foliar injury symptoms are well characterized and considered diagnostic on certain bioindicator plant species. Diagnostic usage for these plants has been verified experimentally in exposure-response studies, using exposure methodologies such as continuous stirred tank reactors, open-top chambers (OTCs), and free-air carbon dioxide (and ozone) enrichment (FACE). Although there remains a lack of robust exposure-response functions that would allow prediction of visible foliar injury severity and incidence under varying air quality and environmental conditions, ''experimental evidence has clearly established a consistent association of the presence of visible foliar injury symptoms with O_3 exposure, with greater exposure often resulting in greater and more prevalent injury'' (U.S. EPA, 2013a, section 9.4.2, p. 9–41). The research newly available in this review includes: 1) controlled exposure studies conducted to test and verify the O_3

[184] The SUM06 index is a threshold-based approach described as the sum of all hourly O_3 concentrations greater or equal to 0.06 ppm observed during a specified daily and seasonal time window (U.S. EPA, 2013a, section 9.5.2). The W126 index is a non-threshold approach described as the sigmoidally weighted sum of all hourly O_3 concentrations observed during a specified daily and seasonal time window, where each hourly O_3 concentration is given a weight that increases from zero to one with increasing concentration (U.S. EPA, 2013a, section 9.5.2).

[185] In describing the form as ''seasonal'', the EPA is referring generally to the growing season of O_3-sensitive vegetation, not to the seasons of the year (*i.e.,* spring, summer, fall, winter).

sensitivity and response of potential new bioindicator plant species; 2) multi-year field surveys in several National Wildlife Refuges (NWR) documenting the presence of foliar injury in valued areas; and 3) ongoing data collection and assessment by the U.S. Forest Service's Forest Health Monitoring Forest Inventory and Analysis (USFS FHM/FIA) program, including multi-year trend analysis (U.S. EPA, 2013a, section 9.4.2). These recent studies, in combination with the entire body of available evidence, thus form the basis for the ISA determinations of a causal relationship between ambient O_3 exposure and the occurrence of O_3-induced visible foliar injury on sensitive vegetation across the U.S. (U.S. EPA, 2013a, p. 9–42).

Recently available evidence confirms the evidence available in previous reviews that visible foliar injury can occur when sensitive plants are exposed to elevated O_3 concentrations in a predisposing environment (*i.e.,* adequate soil moisture) (U.S. EPA, 2013a, section 9.4.2). Recent evidence also continues to support previous findings that indicated the occurrence of visible foliar injury at cumulative ambient O_3 exposures previously examined.

With regard to evidence from controlled exposure studies, a recent study, using continuously stirred tank reactor chambers, evaluated the occurrence of O_3 characteristic visible foliar injury symptoms on 28 species of plants that were suspected of being O_3 sensitive and most of which grow naturally throughout the northeast and midwest U.S., including in national parks and wilderness areas (U.S. EPA, 2013a, section 9.4.2.1; Kline et al., 2008). Across the 28 tested species, the study reported O_3-induced responses in 12, 20, 28 and 28 species at the 30, 60, 90 and 120 ppb exposure concentrations,[186] respectively; the plants were exposed for 7 hours per each weekday over 21 to 29 summer days (Kline et al., 2008).

A string of recently published multi-year field studies provide a complementary line of field-based evidence by documenting the incidence of visible foliar injury symptoms on a variety of O_3-sensitive species over multiple years and across a range of cumulative, seasonal exposure values in several eastern and midwestern NWRs (U.S. EPA, 2013a, section 9.4.2.1; Davis and Orendovici, 2006; Davis, 2007a, b; Davis, 2009). Some of these studies also included information regarding soil moisture stress using the Palmer Drought Severity Index (PDSI). While environmental conditions and species varied across the four NWRs, visible foliar injury was documented to a varying degree at each site.

By far the most extensive field-based dataset of visible foliar injury incidence is that obtained by the USFS FHM/FIA biomonitoring network program. A trend analysis of data from the sites located in the Northeast and North Central U.S. for the 16 year period from 1994 through 2009 (Smith, 2012) describes evidence of visible foliar injury occurrence in the field as well as some insight into the influence of changes in air quality and soil moisture on visible foliar injury and the difficulty inherent in predicting foliar injury response under different air quality/soil moisture scenarios (Smith, 2012; U.S. EPA, 2013a, section 9.2.4.1). Study results showed that incidence and severity of foliar injury were dependent on local site conditions for soil moisture availability and O_3 exposure. Overall, there was a declining trend in the incidence of visible foliar injury as peak O_3 concentrations declined, although the study additionally indicated that moderate O_3 exposures continued to cause visible foliar injury at sites throughout the region (U.S. EPA, 2013a, p. 9–40). In a similar assessment of the USFS FHM/FIA data in the West, six years (2000 to 2005) of biomonitoring data, during a period where a large proportion of California sites did not meet the current standard, indicated O_3-related visible foliar injury in 25–37% of biosites in California (Campbell et al., 2007; U.S. EPA, 2013a, section 9.4.2.1).[187] These recent studies provide additional evidence of O_3-induced visible foliar injury in many areas across the U.S. and augment the EPA's understanding of O_3-related visible foliar injury and of factors, such as soil moisture, that influence associations between O_3 exposures or concentrations and visible foliar injury.

b. Effects on Forest Tree Growth, Productivity and Carbon Storage

Ozone has been shown to affect a number of important U.S. tree species with respect to growth, productivity, and carbon storage. Ambient O_3 concentrations have long been known to cause decreases in photosynthetic rates and plant growth. As discussed in the ISA, research published since the 2006 AQCD substantiates prior conclusions regarding O_3-related effects on forest tree growth, productivity and carbon storage. The ISA states, ''previous O_3 AQCDs concluded that there is strong evidence that exposure to O_3 decreases photosynthesis and growth in numerous plant species'' and that ''[s]tudies published since the 2008 review support those conclusions'' (U.S. EPA, 2013a, p. 9–42). The available studies come from a variety of different study types that cover an array of different species, effects endpoints, levels of biological organization and exposure methods and durations. The O_3-induced effects at the plant scale may translate to the ecosystem scale, with changes in productivity and carbon storage. As stated in the ISA, ''[s]tudies conducted during the past four decades have demonstrated unequivocally that O_3 alters biomass allocation and plant reproduction'' (U.S. EPA, 2013a, p. 1–10).

The previously available strong evidence for trees includes robust E–R functions for seedling relative biomass loss (RBL)[188] in 11 species developed under the National Health and Environmental Effects Research Laboratory-Western Ecology Division program. This series of experiments used OTCs to study seedling growth response for a single growing season under a variety of O_3 exposures (ranging from near background to well above current ambient concentrations) and growing conditions (U.S. EPA, 2013a, section 9.6.2; Lee and Hogsett, 1996). The evidence from these studies shows that there is a wide range in sensitivity across the studied species in the seedling growth stage over the course of a single growing season, with some species being extremely sensitive and others being very insensitive over the range of cumulative O_3 exposures studied (U.S. EPA, 2014c, Figure 5–1). At the other end of the organizational spectrum, field-based studies of species growing in natural stands have compared observed plant response across a number of different sites and/or years when exposed to varying ambient O_3 exposure conditions. For example, a study conducted in forest stands in the southern Appalachian Mountains during a period when O_3 concentrations exceeded the current standard found that the cumulative

[186] Two of the target exposure levels, 30 and 60 ppb, fall below the level of the current standard (75 ppb), although the exposures were average concentrations for 7-hour exposures across durations shorter than a month. Because the form of the current standard targets peak concentrations in a season, an area that just meets the current standard can be expected to have mean concentrations well below that level due to variability in ambient O_3 concentrations.

[187] See: *http://www.epa.gov/airtrends/values.html.*

[188] These functions for RBL estimate reduction in a year's growth as a percentage of that expected in the absence of O_3 (U.S. EPA, 2013a, section 9.6.2; U.S. EPA, 2014b, section 6.2).

effects of O_3 decreased seasonal stem growth (measured as a change in circumference) by 30–50 percent for most of the examined tree species (*i.e.,* tulip poplar, black cherry, red maple, sugar maple) in a high O_3 year in comparison to a low O_3 year (U.S. EPA, 2013a, section 9.4.3.1; McLaughlin et al., 2007a). The study also reported that high ambient O_3 concentrations can increase whole-tree water use and in turn reduce late-season streamflow (McLaughlin et al., 2007b; U.S. EPA, 2013a, p. 9–43).

The magnitude of O_3 impact on ecosystem productivity and on forest composition can vary among plant communities based on several factors including: the type of stand or community in which the sensitive species occurs (*e.g.,* single species *versus* mixed canopy), the role or position of the species in the stand (*e.g.,* dominant, sub-dominant, canopy, understory), the sensitivity of co-occurring species and environmental factors (*e.g.,* drought and other factors). For example, O_3 has been found to have little impact on white fir, but to greatly reduce growth of ponderosa pine in southern California, and cause decreased net primary production of most forest types in the Mid-Atlantic region, although only small impacts on spruce-fir forest (U.S. EPA, 2013a, section 9.4.3.4).

As noted above, long-standing evidence has demonstrated that O_3 alters biomass allocation and plant reproduction (U.S. EPA, 2013a, section 9.4.3). Several studies published since the 2006 O_3 AQCD further demonstrate that O_3 can alter reproductive processes in herbaceous and woody plant species, such as the timing of flowering and the number of flowers, fruits and seeds (U.S. EPA, 2013a, section 9.4.3.3). Further, limited evidence in previous reviews reported that vegetation effects from a single year of exposure to elevated O_3 could be observed in the following year. For example, growth affected by a reduction in carbohydrate storage in one year may result in the limitation of growth in the following year. Such ''carry-over'' effects have been documented in the growth of some tree seedlings and in roots (U.S. EPA, 2013a, section 9.4.8; Andersen, et al., 1997). In the current review, additional field-based evidence expands the EPA's understanding of the consequences of single and multi-year O_3 exposures in subsequent years. A number of studies were conducted at a planted forest at the Aspen FACE site in Wisconsin. These studies, which occurred in a field setting (more similar to natural forest stands than OTC studies), observed tree growth responses when grown in single or two species stands within 30-m diameter rings and exposed over a period of ten years to existing ambient conditions and elevated O_3 concentrations. Some studies indicate the potential for carry-over effects, such as those showing that the effects of O_3 on birch seeds (reduced weight, germination, and starch levels) could lead to a negative impact on species regeneration in subsequent years, and that the effect of reduced aspen bud size might have been related to the observed delay in spring leaf development. These effects suggest that elevated O_3 exposures have the potential to alter carbon metabolism of overwintering buds, which may have subsequent effects in the following year (Darbah, et al., 2008, 2007; Riikonen et al., 2008; U.S. EPA, 2013a, section 9.4.3). Other studies found that, in addition to affecting tree heights, diameters, and main stem volumes in the aspen community, elevated O_3 over a 7-year study period was reported to increase the rate of conversion from a mixed aspen-birch community to a community dominated by the more tolerant birch, leading the authors to conclude that elevated O_3 may alter intra- and inter-species competition within a forest stand (U.S. EPA, 2013a, section 9.4.3; Kubiske et al., 2006; Kubiske et al., 2007). These studies confirm earlier FACE results of aspen growth reductions from a 6–7 year exposure to elevated O_3 and of cumulative biomass impacts associated with changes in annual production in studied tree communities (U.S. EPA, 2013a, section 9.4.3; King et al., 2005).

In addition to individual studies, recent meta-analyses have quantitatively analyzed the effect of O_3 on trees across large numbers of studies. In particular, a recent meta-analysis of 55 peer reviewed studies from the past 40 years indicates a negative relationship between O_3 concentrations in the northern hemisphere during that period and stomatal conductance and photosynthesis, which decreases growth (U.S. EPA, 2013a, section 9.4.3.1; Wittig et al., 2007). In this analysis, younger trees (less than 4 years) were affected less by O_3 than older trees (U.S. EPA, 2013a, section 9.4.3.1; Wittig, et al., 2007). A second meta-analysis that quantitatively compiled 263 peer-reviewed studies ''demonstrates the coherence of O_3 effects across numerous studies and species that used a variety of experimental techniques, and these results support the conclusion of the previous AQCD that exposure to O_3 decreases plant growth'' (U.S. EPA, 2013a, p. 9–43). Other meta-analyses have examined the effect of O_3 exposure on root growth and generally found that O_3 exposure reduced carbon allocated to roots (U.S. EPA, 2013a, pp. 9–45 to 9–46).

As noted above, robust E–R functions have been developed for 11 tree species (black cherry, Douglas fir, loblolly pine, ponderosa pine, quaking aspen, red alder, red maple, sugar maple, tulip poplar, Virginia pine, white pine) from the extensive evidence base of O_3–induced growth effects that was also available and relied upon in the previous review. While the species for which robust E–R functions have been developed represent only a small fraction (0.8 percent) of the total number of native tree species in the contiguous U.S. (1,497), this small subset includes eastern and western species, deciduous and coniferous species, and species that grow in a variety of ecosystems and represent a range of tolerance to O_3 (U.S. EPA, 2013a, section 9.6.2; U.S. EPA, 2014b, section 6.2, Figure 6–2, Table 6–1). Each of these species were studied in OTCs, with most species studied multiple times under a wide range of exposure and/or growing conditions, with separate E–R functions developed for each combination of species, exposure condition and growing condition scenario. These species-specific composite E–R functions have been successfully used to predict the biomass loss response from tree seedling species over a range of cumulative exposure conditions (U.S. EPA, 2013a, section 9.6.2). The 11 robust composite E–R functions available in the last review, as well as the E–R for eastern cottonwood (derived from a field study in which O_3 and climate conditions were not controlled), are described in the ISA and graphed in the WREA to illustrate the predicted responses of these species over a wide range of cumulative exposures (U.S. EPA, 2014b, section 6.2, Table 6–1 and Figure 6–2; U.S. EPA, 2013a, section 9.6.2). For some of these species, the E–R function is based on a single study (*e.g.,* red maple), while for other species there were as many as 11 studies available (ponderosa pine). In total, the E–R functions developed for these 12 species (the 11 with robust composite E–R functions plus eastern cottonwood) reflect 52 tree seedling studies. A stochastic analysis in WREA, summarized in section IV.C below, indicates the potential for within species variability to contribute appreciably to estimates for each species. Consideration of biomass loss estimates in the PA and in discussions

below, however, is based on conventional method and focuses on estimates for the 11 species for which the robust datasets from OTC experiments are available, in consideration of CASAC advice.[189]

c. Crop Yield Loss

The ''detrimental effect of O_3 on crop production has been recognized since the 1960s'' (U.S. EPA, 2013a, p. 1–10, section 9.4.4). On the whole, the newly available evidence supports previous conclusions that exposure to O_3 decreases growth and yield of crops. The ISA describes average crop yield loss reported across a number of recently published meta-analyses and identifies several new exposure studies that support prior findings for a variety of crops of decreased yield and biomass with increased O_3 exposure (U.S. EPA, 2013a, section 9.4.4.1, Table 9–17). Studies have also ''linked increasing O_3 concentration to decreased photosynthetic rates and accelerated aging in leaves, which are related to yield'' and described effects of O_3 on crop quality, such as nutritive quality of grasses, macro- and micronutrient concentrations in fruits and vegetable crops and cotton fiber quality (U.S. EPA, 2013a, p. 1–10, section 9.4.4). The findings of the newly available studies do not change the basic understanding of O_3-related crop yield loss since the last review and little additional information is available in this review on factors that influence associations between O_3 levels and crop yield loss (U.S. EPA, 2013a, section 9.4.4.).

The new evidence has strengthened support for previously established E–R functions for 10 crops (barley, field corn, cotton, kidney bean, lettuce, peanut, potato, grain sorghum, soybean and winter wheat), reducing two important areas of uncertainty, especially for soybean. The established E–R functions were developed from OTC-type experiments (U.S. EPA, 2013a, section 9.6.3; U.S. EPA, 2014b, section 6.2; U.S. EPA, 2014c, Figure 5–4). In this review, the ISA included an analysis comparing OTC data for soybean from the National Crop Loss Assessment Network (NCLAN) with field-based data from SoyFACE (Soybean Free Air Concentration Enrichment) studies (U.S. EPA, 2013a, section 9.6.3.1).[190] Yield loss in soybean from O_3 exposure at the SoyFACE field experiment was reliably predicted by soybean E–R functions developed from NCLAN data, demonstrating a robustness of the E–R functions developed with NCLAN data to predict relative yield loss from O_3 exposure. A second area of uncertainty that was reduced is that regarding the application of the NCLAN E–R functions, developed in the 1980s, to more recent cultivars currently growing in the field. Recent studies, especially those focused on soybean, provide little evidence that crops are becoming more tolerant of O_3 (U.S. EPA, 2006a; U.S. EPA, 2013a). A meta-analysis of 53 studies found consistent deleterious effects of O_3 exposures on soybean from studies published between 1973 and 2001 (Morgan et al., 2003). Further, Betzelberger et al. (2010) utilized the SoyFACE facility to compare the impact of elevated O_3 concentrations across 10 soybean cultivars to investigate intraspecific variability of the O_3 response, finding that the E–R functions derived for these 10 current cultivars were similar to the response functions derived from the NCLAN studies conducted in the 1980s (Heagle, 1989), ''suggesting there has not been any selection for increased tolerance to O3 in more recent cultivars'' (U.S. EPA, 2013a, p. 9–59). Additionally, the ISA comparisons of NCLAN and SoyFACE data referenced above ''confirm that the response of soybean yield to O_3 exposure has not changed in current cultivars'' (U.S. EPA, 2013a, p. 9–59; section 9.6.3.1). Thus, the evidence available in the current review has reduced uncertainties in two areas with regard to the use of E–R functions for soybean crop yield loss.

During past O_3 NAAQS reviews, there were very few studies that estimated O_3 impacts on crop yields at large geographical scales (*i.e.,* regional, national or global). Recent modeling studies of the impact of O_3 concentrations historically found that increased O_3 in the past generally reduced crop yield, but the impacts varied across regions and crop species, with the largest O_3-induced crop yield losses estimated to have occurred in high-production areas that had been exposed to elevated O_3 concentrations, such as the Midwest and the Mississippi Valley regions of the U.S. (U.S. EPA, 2013a, Section 9.4.4.1). Among affected crop species, the estimated yield loss for wheat and soybean were higher than rice and maize (*i.e.,* field corn). Additionally, satellite and ground-based O_3 measurements have assessed soybean yield loss estimated to result from O_3 over the continuous area of Illinois, Iowa, and Wisconsin, finding a relationship which correlates well with the previous results from FACE- and OTC-type experiments (U.S. EPA, 2013a, section 9.4.4.1).

Thus, consistent with the conclusions of the 1996 and 2006 CDs, the current ISA concludes that O_3 concentrations in ambient air can reduce the yield of major commodity crops in the U.S. and focuses on use of crop E–R functions based on OTC experiments to characterize the quantitative relationship between ambient O_3 concentrations and yield loss (U.S. EPA, 2013a, section 9.4.4). In the PA, as summarized in sections IV.D and IV.E below, relative yield loss (RYL) is estimated for 10 different crops using the individual E–R functions described in the WREA [191] (U.S. EPA, 2014b, section 6.2; U.S. EPA, 2014c, section 6.3).

2. Potential Impacts on Public Welfare

The magnitude of a public welfare impact or the degree to which it may be considered adverse is dependent upon the nature and severity of the specific welfare or ecological effect, the use or service (and value) of the affected ecosystem and the relevance and significance of that use [192] to the public welfare. In the preamble of the 2012 final notice of rulemaking on the secondary standards for oxides of nitrogen and sulfur (NOx/SOx), the EPA stated that ''[a]n evaluation of adversity to the public welfare might consider the likelihood, type, magnitude, and spatial scale of the effect, as well as the potential for recovery and any uncertainties relating to these conditions'' (77 FR 20232, April 3,

[189] The CASAC cautioned EPA against placing too much emphasis on the eastern cottonwood data, stating that while the cottonwood data are important results, they are not as strong as those from other experiments that developed E–R functions based on controlled O_3 exposure in OTCs; they are from a single gradient study that did not control for O_3 and climatic conditions and they show extreme sensitivity to O_3 compared to other studies (Frey, 2014c, p. 10).

[190] The NCLAN program, which was undertaken in the early to mid-1980s, assessed multiple U.S. crops, locations, and O_3 exposure levels, using consistent methods, to provide the largest, most uniform database on the effects of O_3 on agricultural crop yields (U.S. EPA 1996a; U.S. EPA, 2006a; U.S. EPA, 2013a, sections 9.2, 9.4, and 9.6, Frey, 2014c, p. 9). The SoyFACE experiment was a chamberless (or free-air) field-based exposure study conducted in Illinois from 2001–2009 (U.S. EPA, 2013a, section 9.2.4).

[191] These functions for RYL estimate reduction in a year's growth as a percentage of that expected in the absence of O_3 (U.S. EPA, 2013a, section 9.6.2; U.S. EPA, 2014b, section 6.2).

[192] Ecosystem services have been defined as ''the benefits that people obtain from ecosystems'' (U.S. EPA, 2013a, Preamble, p. 1xxii; UNEP, 2003) and thus are an aspect of the use of a type of vegetation or ecosystem. Similarly, a definition used for the purposes of EPA benefits assessments states that ecological goods and services are the ''outputs of ecological functions or processes that directly or indirectly contribute to social welfare or have the potential to do so in the future'' and that ''[s]ome outputs may be bought and sold, but most are not marketed'' (U.S. EPA, 2006b).

2012). The EPA additionally stated that ''[c]onceptually, changes in ecosystem services may be used to aid in characterizing a known or anticipated adverse effect to public welfare'' (77 FR 20232, April 3, 2012).[193]

Potential public welfare impacts associated with ecosystems and associated services have a range of dimensions, including spatial, temporal, and social, and these likely will vary depending on the type of effect being characterized. For example, ecosystems can cover a range of spatial scales, and the services they provide can accrue locally or be distributed more broadly, such as when crops are sold and eaten locally and/or also sold in regional, national and world markets. Accordingly, impacts can be localized or more widely distributed. Further, ecosystem services can be realized over a range of temporal scales from immediate up to longer term. The size of the societal unit receiving benefits from ecosystem services can also vary dramatically. For example, a national park can provide direct recreational services to the thousands of visitors that come each year, but also provide an indirect value to the millions who may not visit but receive satisfaction from knowing it exists and is preserved for the future (U.S. EPA, 2014b, chapter 5, section 5.5.1).

As recognized in the last review, judgments regarding adverse effects to the public welfare depend on the intended use for and significance of the affected vegetation, ecological receptors, ecosystems and resources to the public welfare (73 FR 16496, March 27, 2008).[194] For example, a number of different types of locations provide services of special significance to the public welfare. As emphasized in previous O_3 NAAQS decisions, and summarized in section IV.A above, Class I areas and other parks have been afforded special federal protection to preserve services that provide for the enjoyment of these resources for current and future generations. Surveys have indicated that Americans rank as very important the existence of the resource, the option or availability of the resource and the ability to bequest or pass on to future generations (Cordell *et al.,* 2008). These and other services provided by Class I areas and other areas that have been afforded special protection can flow in part or entirely from the vegetation that grows there. Aesthetic value and outdoor recreation depend on the perceived scenic beauty of the environment. Many outdoor recreation activities directly depend on the scenic value of the area, in particular scenic viewing, wildlife-watching, hiking, and camping (U.S. EPA, 2014b, chapters 5 and 7). Further, analyses have reported that the American public values—in monetary as well as nonmonetary ways—the protection of forests from air pollution damage. In fact, studies that have assessed willingness-to-pay for spruce-fir forest protection in the southeastern U.S. from air pollution and insect damage have found that values held by the survey respondents for the more abstract services (existence, option and bequest) were greater than those for recreation or other services (U.S. EPA, 2014b, Table 5–6; Haefele et al., 1991; Holmes and Kramer, 1995).

There are several potential public welfare impacts related to the three main categories of O_3 effects on vegetation (*i.e.,* effects on tree growth, productivity and carbon storage; crop yield loss; and, visible foliar injury, as described in section IV.B.1 above) and their associated ecosystem services. At the same time, these three categories of effects differ with regard to aspects important to judging their public welfare significance. Judgments regarding crop yield loss, for example, depend on considerations related to the heavy management of agriculture in the U.S., while judgments regarding the other categories of effects generally relate to considerations regarding forested areas. For example, while both tree growth-related effects and visible foliar injury have the potential to be significant to the public welfare through impacts in Class I and other protected areas, they differ in how they might be significant and with regard to the clarity of the data which describes the relationship between the effect and the services potentially affected.

With regard to effects on tree growth, reduced growth is associated with effects on an array of ecosystem services including reduced productivity, altered forest and forest community (plant, insect and microbe) composition, reduced carbon storage and altered water cycling (U.S. EPA, 2013a, Figure 9–1, sections 9.4.1.1 and 9.4.1.2; U.S. EPA, 2014b, section 6.1). For example, forest or forest community composition can be affected through O_3 effects on growth and reproductive success of sensitive species in the community, with the extent of compositional changes dependent on factors such as competitive interactions (U.S. EPA, 2013a, sections 9.4.3 and 9.4.3.1). Depending on the type and location of the affected ecosystem, services benefitting the public in other ways can be affected as well. For example, other services valued by people that can be affected by reduced tree growth, productivity and carbon storage include aesthetic value, food, fiber, timber, other forest products, habitat, recreational opportunities, climate and water regulation, erosion control, air pollution removal, hydrologic and fire regime stabilization (U.S. EPA 2013a, sections 9.4.1.1 and 9.4.1.2; U.S. EPA, 2014b, section 6.1, Figure 6–1, section 6.4, Table 6–13). Further, impacts on some of these services (*e.g.,* forest or forest community composition) may be considered of greater public welfare significance when occurring in Class I or other protected areas.

Consideration of the magnitude of tree seedling growth effects that might cause or contribute to adverse effects for trees, forests, forested ecosystems or the public welfare is complicated by aspects of, or limitations in, the available information. For example, the evidence on tree seedling growth effects, deriving from the E–R functions for 11 species, provides no clear threshold or breakpoint in the response to O_3 exposure. Additionally, there are no established relationships between magnitude of tree seedling growth reduction and forest ecosystem impacts and, as noted in section IV.B.1.b above, other factors can influence the degree to which O_3-induced growth effects in a sensitive species affect forest and forest community composition and other ecosystem service flows from forested ecosystems. These include: 1) the type of stand or community in which the sensitive species is found (*i.e.,* single species versus mixed canopy); 2) the role or position the species has in the stand (*i.e.,* dominant, sub-dominant, canopy, understory); 3) the O_3 sensitivity of the other co-occurring species (O_3 sensitive or tolerant); and 4) environmental factors, such as soil moisture and others. The lack of such established relationships complicates judgments as to the extent to which different amounts of tree seedling growth would be significant to the public welfare and thus an important consideration in the level of protection for the secondary standard.

During the 1997 review of the secondary standard, views related to

[193] Ecosystem services analyses were one of the tools used in that review to inform the decisions made with regard to adequacy and as such, were used in conjunction with other considerations in the discussion of adversity to public welfare (77 FR 20241).

[194] As noted in section IV.A above, in judgments regarding public welfare significance in the last review, emphasis was placed on vegetation and ecosystem effects to sensitive species that are known to or are likely to occur in federally protected areas such as national parks and other Class I areas, or on lands set aside by states, tribes and public interest groups to provide similar benefits to the public welfare (73 FR 16496, March 27, 2008; 75 FR 3023–24, January 19, 2010).

this issue were provided by a 1996 workshop of 16 then-leading scientists in the context of discussing their views for a secondary O_3 standard (Heck and Cowling, 1997). In their consideration of tree growth effects as an indicator for forest ecosystems and crop yield reduction as an indicator of agricultural systems, the workshop participants identified annual percentages, of RBL for forest tree seedlings and RYL for agricultural crops, considered important to their judgments on the standard. With regard to forest ecosystems and seedling growth effects as an indicator, the participants selected a range of 1–2% RBL per year ''to avoid cumulative effects of yearly reductions of 2%.'' With regard to crops, they indicated an interest in protecting against crop yield reductions of 5% RYL yet noted uncertainties surrounding such a percentage which led them to identifying 10% RYL for the crop yield endpoint (Heck and Cowling, 1997). The workshop report provides no explicit rationale for the percentages identified (2% RBL and 5% or 10% RYL); nor does it describe their connection to ecosystem impacts of a specific magnitude or type and judgments on significance of the effects for public welfare, *e.g.,* taking into consideration the intended use and significance of the affected vegetation (Heck and Cowling, 1997). In recognition of the complexity of assessing the adversity of tree growth effects and effects on crop yield in the broader context of public welfare, the EPA's consideration of those effects in both the 1997 and 2008 reviews extended beyond the consideration of various benchmark responses for the studied species, and with regard to crops, additionally took note of their extensive management (62 FR 38856, July 18, 1997; 73 FR 16436, March 27, 2008).

While, as noted above, public welfare benefits of forested lands can be particular to the type of area in which the forest occurs, some of the potential public welfare benefits associated with forest ecosystems are not location dependent. A potentially extremely valuable ecosystem service provided by forested lands and for which the ISA concludes a likely causal relationship with O_3 in ambient air is carbon storage, a regulating service that is ''of paramount importance for human society'' (U.S. EPA, 2013a, section 2.6.2.1 and p. 9–37). The service of carbon storage is potentially important to the public welfare no matter in what location the sensitive trees are growing, or what their intended current or future use. In other words, the benefit exists as long as the tree is growing, regardless of what additional functions and services it provides.

Another example of locations potentially vulnerable to O_3-related impacts but not necessarily identified for such protection might be forested lands, both public and private, where trees are grown for timber production, particularly where they are dominated by a single timber species stand that is sensitive to O_3, such as ponderosa pine. Further, forests in urbanized areas provide a number of services that are important to the public in those areas, including air pollution removal, cooling of the heat island effect, and beautification (U.S. EPA, 2014b, section 6.6.2 and Appendix 6D; Akbari, 2002).[195] The presence of O_3-sensitive trees in such areas may place them at risk from elevated O_3 exposures, contributing to potential impacts on important services provided by urban forests (U.S. EPA, 2014b, sections 6.6.2 and 6.7). There are many other tree species, such as species used in the USFS biomonitoring network, and various ornamental and agricultural species (*i.e.,* Christmas trees, fruit and nut trees) that provide ecosystem services that may be judged important to the public welfare but whose vulnerability to impacts from O_3 on tree growth, productivity and carbon storage has not been quantitatively characterized (U.S. EPA, 2014b, Chapter 6; Abt Associates, 1995).

As noted above, in addition to tree growth-related effects, O_3-induced visible foliar injury also has the potential to be significant to the public welfare through impacts in Class I and other similarly protected areas. Visible foliar injury is a visible bioindicator of O_3 exposure in species sensitive to this effect, with the injury affecting the physical appearance of the plant. Accordingly visible foliar injury surveys are used by federal land managers as tools in assessing potential air quality impacts in Class I areas. These surveys may focus on plant species that have been identified as potentially sensitive air quality related values (AQRVs) due to their sensitivity to O_3-induced foliar injury (USFS, NPS, FWS, 2010). An AQRV is defined by the National Park Services as a ''resource, as identified by the FLM for one or more Federal areas that may be adversely affected by a change in air quality'' and the resource ''may include visibility or a specific scenic, cultural, physical, biological, ecological, or recreational resource identified by the FLM for a particular area'' (USFS, NPS, USFWS, 2010).[196] No criteria have been established, however, regarding a level or prevalence of visible foliar injury considered to be adverse to the affected vegetation, and, as noted in section IV.B.1.a above, there is not a clear relationship between visible foliar injury and other effects, such as reduced growth and productivity. Thus, key considerations with regard to public welfare significance of this endpoint have related to qualitative consideration of the plant's aesthetic value in protected forested areas. Depending on the extent and severity, O_3-induced visible foliar injury might be expected to have the potential to impact the public welfare in scenic and/or recreational areas during the growing season, particularly in areas with special protection, such as Class I areas.

The ecosystem services most likely to be affected by O_3-induced visible foliar injury (some of which are also recognized above for tree growth-related effects) are cultural services, including aesthetic value and outdoor recreation. In addition, several tribes have indicated that many of the species identified as O_3-sensitive (including bioindicator species) are culturally significant (U.S. EPA, 2014c, Table 5–1). The geographic extent of protected areas that may be vulnerable to such public welfare effects of O_3 is potentially appreciable. Sixty six species that occur on U.S. National Park Service (NPS) and U.S. Fish and Wildlife Service lands[197] have been identified as sensitive to O_3-induced visible foliar injury and some also have particular cultural importance to some tribes (U.S. EPA, 2014c, Table 5–1 and Appendix 5–A; U.S. EPA, 2014b, section 6.4.2). Not all species are equally sensitive to O_3, however, and quantitative relationships between O_3 exposure and other important effects, such as seedling growth reduction, are

[195] For example, see *http://www.fs.fed.us/research/urban/environmental-justice.php.*

[196] The identification, monitoring and assessment of AQRVs with regard to an adverse effect is an approach used for assessing the potential for air pollution impacts from pending permit actions in Class I areas (USFS, NPS, USFWS, 2010). An adverse impact is recognized by the National Park Service as one that results in diminishment of the Class I areas's national significance or the impairment of the ecosystem structure or functioning, as well as impairment of the quality of the visitor experience (USFS, NPS, USFWS, 2010). Federal land managers (FLMs) make such adverse impact determinations on a case-by-case basis, using technical and other information which they provide for consideration by permitting authorities. The National Park Services has developed is a document describing an overview of approaches related to assessing projects under the National Environmental Policy Act and other planning initiatives affecting the National Park System (*http://www.nature.nps.gov/air/Pubs/pdf/AQGuidance_2011–01–14.pdf*).

[197] See *http://www2.nature.nps.gov/air/Pubs/pdf/flag/NPSozonesensppFLAG06.pdf.*

only available for a subset of the 66, as described in section IV.B.1. above. A diverse array of ecosystem services has been identified for these twelve species (U.S. EPA, 2014c, Table 5–1). Two of the species in this group that are relatively more sensitive with regard to effects on growth are the ponderosa pine and quaking aspen (U.S. EPA, 2014b, section 6.2), the ranges for which overlap with many lands that are protected or preserved for enjoyment of current and future generations (consistent with the discussion above on Class I and other protected areas), including such lands located in the west and southwest regions of the U.S. where ambient O_3 concentrations and associated cumulative seasonal exposures can be highest (U.S. EPA, 2014c, Appendix 2B).[198]

With regard to agriculture-related effects, the EPA has recognized other complexities, stating that the degree to which O_3 impacts on vegetation that could occur in areas and on species that are already heavily managed to obtain a particular output (such as commodity crops or commercial timber production) would impair the intended use at a level that might be judged adverse to the public welfare has been less clear (73 FR 16497, March 27, 2008; 75 FR 3024; January 19, 2010). We note that while having sufficient crop yields is of high public welfare value, important commodity crops are typically heavily managed to produce optimum yields. In light of all of the inputs that go into achieving these yields, such as fertilizer, herbicides, pesticides, and irrigation, it is difficult to determine at what point O_3-induced yield loss creates an adverse impact for the producer in the way of requiring increased inputs in order to maintain the desired yields. Moreover, based on the economic theory of supply and demand, increases in crop yields would be expected to result in lower prices for affected crops and their associated goods, which would primarily benefit consumers. Given these competing impacts on producers and consumers, it is unclear how to consider these effects in terms of potential adversity to the public welfare (U.S. EPA, 2014c, sections 5.3.2 and 5.7).

When agricultural impacts or vegetation effects in other areas are contrasted with the emphasis on forest ecosystem effects in Class I and similarly protected areas, it can be seen that the Administrator has in past reviews judged the significance to the public welfare of O_3-induced effects on sensitive vegetation growing within the U.S. to differ depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located, with greater significance ascribed to areas identified for specific uses and benefits to the public welfare, such as Class I areas, than to areas for which such uses have not been established. In summary, several considerations are recognized as important to judgments on the public welfare significance of the array of effects of different O_3 exposure conditions on vegetation. While there are complexities associated with the consideration of the magnitude of key vegetation effects that might be concluded to be adverse to ecosystems and associated services, there are numerous locations where O_3-sensitive tree species are present that may be vulnerable to impacts from O_3 on tree growth, productivity and carbon storage and their associated ecosystems and services. It is not possible to generalize across all studied species regarding which cumulative exposures are of greatest concern, however, as this can vary by situation due to differences in exposed species sensitivity, the importance of the observed or predicted O_3-induced effect, the role that the species plays in the ecosystem, the intended use of the affected species and its associated ecosystem and services, the presence of other co-occurring predisposing or mitigating factors, and associated uncertainties and limitations. These factors contribute to the complexity of the Administrator's judgments regarding the adversity of known and anticipated effects to the public welfare.

C. Exposure and Risk Assessment Information

The WREA characterized ambient O_3 exposure and its relationship to tree biomass loss, crop yield loss, and visible foliar injury and the associated ecosystem services [199] in national-scale and case study analyses. The WREA also qualitatively assessed impacts to some ecosystem services, including impacts on the hydrologic cycle, pollination regulation, and fire regulation; commercial non-timber forest products and insect damage; and aesthetic and non-use values. In the quantitative analyses, the WREA characterized effects associated with exposures to O_3 in ambient air using the W126 metric.

The following sections summarize the analyses and adjustment approach used to develop the O_3 concentrations used as inputs to the vegetation risk analyses for tree biomass and crop yield loss, and the analyses, including key results and uncertainties, for tree seedling growth, productivity, carbon storage and associated ecosystem services (section IV.C.2); crop yield loss (section IV.C.3); and visible foliar injury (section IV.C.4).

1. Air Quality Analyses

The WREA evaluated O_3 exposure and risks for several national-scale air quality scenarios: recent conditions (2006 to 2008),[200] the current secondary standard, and W126 index values of 15 ppm-hrs, 11 ppm-hrs, and 7 ppm-hrs, using three-year averages (U.S. EPA, 2014b, chapter 4). For each of these scenarios, three-year average W126 index values were estimated at each 12 km by 12 km grid cell in a national-scale spatial surface. Additionally, some analyses were based on single-year surfaces.[201] The method for creating the five scenarios generally involved two steps (summarized in Table 5–4 of the PA). The first is derivation of the average W126 index value (across the three years) at each monitor location. This value is based on unadjusted O_3 concentrations from monitoring data for recent conditions and adjusted concentrations for the four other scenarios. Concentrations were adjusted based on model predicted relationships between O_3 and U.S.-wide emissions reductions in oxides of nitrogen (NOx). The adjusted air quality does not represent an optimized control scenario that just meets the current standard (or target W126 index values for other scenarios), but rather characterizes one potential distribution of air quality across a region when all monitor locations meet the standard (U.S. EPA, 2014b, section 4.3.4.2). The development of adjusted concentrations was done for each of nine regions independently (see U.S. EPA, 2014b, section 4.3.4.1). In the second step, national-scale spatial surfaces (W126 index values for each 12 km x 12 km

[198] Basal area for resident species in national forests and parks are available in files accessible at: *http://www.fs.fed.us/foresthealth/technology/nidrm2012.shtml.*

[199] In its review of drafts of the WREA and PA, the CASAC conveyed support for analyses and considerations of ecosystem services that may be affected by O_3 exposures (Frey, 2014b, 2014c).

[200] Certain visible foliar injury analyses assessed recent conditions from 2006 to 2010 on an annual basis.

[201] An analysis using data from USFS FHM/FIA O_3 biomonitoring sampling sites (''biosites'') and a screening-level assessment in 214 national parks were done using national-scale spatial surfaces of unadjusted O_3 concentrations (in terms of the W126 index) created for each year from 2006 through 2010 using the VNA interpolation technique (U.S. EPA, 2014b, section 4.3.2, Appendix 4A).

grid cell used in the air quality model) were created using the monitor-location values and the Voronoi Neighbor Averaging (VNA) spatial interpolation technique (details on the VNA technique are presented in U.S. EPA, 2014b, Appendix 4A).

In the dataset used to create the recent conditions scenario, the three-year average W126 index values at the monitor locations (before application of the VNA technique) ranged from below 5 ppm-hrs to 48.6 ppm-hrs (U.S. EPA, 2014b, Figure 4–4 and Table 4–3). In the nine modeling regions, the maximum three-year average W126 index values at monitor locations ranged from 48.6 ppm-hrs in the West region down to 6.6 ppm-hrs in the Northwest region.[202] After adjustment of the monitor location concentrations to just meet the current standard in each region (using relationships described above), the region-specific maximum three-year average W126 values ranged from 18.9 ppm-hrs in the West region to 2.6 ppm-hrs in the Northeast region (U.S. EPA, 2014b, Table 4–3). With the next step, creation of the national surface of air quality values at grid cell centroids, the highest values were reduced, such that all the three-year average W126 index values were below 15 ppm-hrs across the national surface with the exception of a very small area of the Southwest region (near Phoenix) where average W126 index values were just above 15 ppm-hrs. Thus, it can be seen that application of the VNA interpolation method to estimate W126 index values at the centroid of every 12 x 12 km^2 grid cell rather than only at each monitor location results in a lowering of the highest values.

Because the W126 estimates generated for the different air quality scenarios assessed are inputs to the vegetation risk analyses for tree biomass and crop yield loss, and also used in the foliar injury analyses, any uncertainties in the air quality analyses are propagated into the those analyses (U.S. EPA, 2014b, section 8.5). The WREA identified sources of uncertainty for the W126 estimates for each air quality scenario and qualitatively characterized the magnitude of uncertainty and potential for directional bias (U.S. EPA, 2014b, Table 4–5). As discussed in Chapter 4 and 8 of the WREA, an important large uncertainty in the analyses is the assumed response of the W126 concentrations to emissions reductions needed to meet the existing standard (U.S. EPA, 2014b, section 8.5.1). Any approach to characterizing O_3 air quality over broad geographic areas based on concentrations at monitor locations will convey inherent uncertainty. The model-based adjustments are based on U.S.-wide emissions reductions in NOx and characterize only one potential distribution of air quality across a region when all monitor locations meet the standard (U.S. EPA, 2014b, section 4.3.4.2).[203] Additionally, the surface is created from the three-year average at the monitor locations, rather than creating a surface for each year and then averaging across years at each grid cell; the potential impact of this on the resultant estimates is considered in the WREA (U.S. EPA, 2014b, Appendix 4A).

An additional uncertainty related to the W126 index value estimates for each air quality scenario comes from the creation of a national W126 surface using the VNA technique to interpolate recent air quality measurements of O_3. In general, spatial interpolation techniques perform better in areas where the O_3 monitoring network is denser. Therefore, the W126 index values estimated in the rural areas in the West, Northwest, Southwest, and West North Central with few or no monitors (U.S. EPA, 2014b, Figure 2–1) are more uncertain than those estimated for areas with denser monitoring. Further, this interpolation method generally underpredicts higher 12-hour W126 exposures. Due to the important influence of higher exposures in determining risks to plants, the potential for the VNA interpolation approach to underpredict higher W126 exposures could result in an underestimation of risks to vegetation in some areas. Underestimation of the highest W126 index values for the current standard scenario is an additional impact of the interpolation method that is important to consider.

2. Tree Seedling Growth, Productivity, Carbon Storage and Associated Ecosystem Services

For the WREA assessments related to tree growth, productivity, carbon storage and associated ecosystem services, the sections below provide an overview of the analyses along with the key results (section IV.C.2.a) and summarize the key uncertainties (section IV.C.2.b).

a. Overview and Summary of Key Results

The assessments to estimate the exposures and risks for tree seedling growth, productivity, and carbon storage reflect a range of spatial scales ranging from the county scale up to the national park, urban area, and national scales. For the air quality scenarios described above, the WREA applied the species-specific E–R functions to develop estimates of O_3-associated RBL, productivity, carbon storage and associated ecosystem services (U.S. EPA, 2014b, Chapter 6). Some analyses also apply the median across species E–R functions.

The WREA examined multiple approaches for characterizing the median tree response to O_3 exposure based on the 11 robust E–R functions for tree seedlings from the OTC research and the E–R function for eastern cottonwood (U.S. EPA, 2014b, section 6.2.1.2 and Figure 6–5). For some species, only one study was available (*e.g.,* red maple), and for other species there were as many as 11 studies available (*e.g.,* ponderosa pine). To illustrate the effect of within-species variability associated with the E–R data available on estimates for a median response across the 12 species, the WREA performed a stochastic sampling analysis involving multiple iterations of random selection of E–R functions from the studies available for each of the 12 species. This analysis produced median values at each cumulative exposure level that were higher than medians derived by two conventional, deterministic methods (U.S. EPA, 2014b, section 6.2.1.2 and Figure 6–5).[204] For example, the median seasonal W126 index value for which a two percent biomass loss is estimated in seedlings for the studied species ranges from approximately 7 ppm-hrs using the conventional methods up to 14 ppm-hrs when derived by the stochastic method. Although the stochastic method provides some illustration of the effect of within–species variability, we focus on the conventional approach that gives equal weight to each studied species,

[202] The regions referenced here and also with regard to monitoring data analyses described in section IV.D.4 below are NOAA climate regions, as shown in Figure 2B–1 of the PA.

[203] The WREA analyses used U.S.-wide NOx emissions reductions to simulate air quality that independently in each region would just meet the existing standard and the three W126 scenarios. The NOx emissions reductions were determined such that the highest monitor within each region would just meet the target level. In this way, the adjustment results in broad regional reductions in O_3 and includes reductions in O_3 at some monitors that were already meeting or below the target level. Thus, the adjustments performed to develop a scenario meeting a target level at the highest monitor in each region did result in substantial reduction below the target level in some areas of the region. This result at the monitors already well below the target indicates an uncertainty with regard to air quality expected from specific control strategies that might be implemented to meet a particular target level.

[204] These methods were calculating a median using the composite functions and calculating a median using all tree seedling studies available.

calculating the median response based on the composite E–R functions, consistent with CASAC advice (Frey, 2014b).

The WREA estimates indicate substantial heterogeneity in plant responses to O_3, both within species, between species, and across regions of the U.S. The tree species known to be O_3-sensitive are different in the eastern and western U.S. and the eastern U.S. has far more such species. Ozone exposure and risk is somewhat easier to assess in the eastern U.S. because of the availability of more data and the greater number of species to analyze. In addition, there are more O_3 monitors in the eastern U.S. but fewer national parks (U.S. EPA, 2014b, chapter 8). In consideration of CASAC advice, the WREA derived RBL and weighted RBL (wRBL) estimates separately with and without the eastern cottonwood. The results summarized here are for the analyses that exclude cottonwood.[205] The WREA reported RBL estimates relative to a benchmark of 2% RBL for tree seedlings, as well as relative to other percent RBL values. The 2% RBL benchmark was considered based on CASAC advice that stated that ''focus on a 2% loss level for trees . . . is appropriate.'' (Frey, 2014b, p. 6). The main WREA analyses for effects related to tree growth, productivity and carbon storage are summarized below, with the key findings for each.

Relative biomass loss nationally was estimated for each of the 12 studied species from the composite E–R functions for each species described above and information on the distribution of those species across the U.S. (U.S. EPA, 2014b, section 6.2.1.3 and Appendix 6A). As one example of a tree species near the median of the studied species, relative biomass loss estimates (reduced growth) for ponderosa pine in the current standard air quality scenario are below two percent for most areas where this species is found but estimates of RBL for this species in some areas of the southwest fall above two percent biomass loss (U.S. EPA, 2014b, Figure 6–8). Maximum estimates of RBL for all areas where ponderosa pine is found decrease to just over three percent and just over two percent for the 15 and 7 ppm-hrs scenarios, respectively (U.S. EPA, 2014b, Table 6–6).

To provide an indication of ecosystem-level impacts, weighted estimates of RBL (wRBL) were also developed for each grid cell nationwide. This is estimated from the species-specific E–R functions and a weighting approach based on information on prevalence of the studied species across the U.S. (*i.e.,* the proportion of the total basal area modeled by USFS across all species for which data were available). An overall wRBL value for each grid cell is generated by summing the wRBL values for each studied tree species found within that grid cell. The wRBL is intended to be an indication of the potential magnitude of the ecological effect that could occur in some ecosystems. In general, the higher the wRBL is in a given ecosystem, the larger the potential ecological effect. (U.S. EPA, 2014b, section 6.8, Table 6–25).

For the national-scale analysis, the WREA presents the percent of total basal area with wRBL greater than 2%. The estimates for the weighted biomass loss analysis reflecting the 11 tree species with robust E–R functions are as follows (U.S. EPA, 2014b, Table 6–25):

- For the current standard scenario, the percent of total basal area that exceeds a two percent wRBL is 0.2 percent.
- For the W126 scenarios of 15, 11 and 7 ppm-hrs, the percent of total basal area that exceeds a two percent wRBL is 0.2 percent, 0.1 percent, and less than 0.1 percent respectively (U.S. EPA, 2014b, Table 6–25).

In the wRBL analysis for Class I areas, the number of Class I areas with wRBL greater than 2% is estimated for the grid cells located in the 145 of the 156 Class I areas for which data were available (U.S. EPA, 2014b, Table 6–26).

- For the current standard scenario, two of the 145 assessed Class I areas have weighted RBL values above two percent (U.S. EPA, 2014b, Table 6–26).
- For the W126 scenarios of 15, 11 and 7 ppm-hrs, there are two, two and one Class I area with wRBL above two percent, respectively.

In the county analysis, the WREA estimated the number of U.S. counties in which any of the studied tree species is estimated to experience more than two percent RBL, the number of species affected, and the number of counties for which the median of the species-specific functions exceeds two percent RBL. In addition to the estimates based on all 12 studied species and also the 11 species with the exclusion of eastern cottonwood (in response to CASAC advice), additional estimates were developed without black cherry to show contribution of that sensitive species to the multi-species estimates (U.S. EPA, 2014b, Table 6–7).

- In the current standard scenarios, 66% of the 3,109 assessed counties are estimated to have at least one of the 11 species (excluding cottonwood) with an RBL greater than two percent, with three counties having three species exceeding two percent. The median RBL (across the species present) is above two percent in 239 counties. The maximum number of species in any one county with an RBL greater than two percent is three (excluding cottonwood). (U.S. EPA, 2014b, Table 6–7).
- For the 15, 11 and 7 ppm-hrs scenarios, the proportion of 3,109 counties with one or more species with an RBL above two percent decreases to 61 percent, 59 percent, and 58 percent, respectively. For the 7 ppm-hrs scenario, the median RBL is above two percent in six percent of the counties (U.S. EPA, 2014b, Table 6–7).
- The county RBL estimates are appreciably influenced by black cherry, a very sensitive species that is widespread in the Eastern U.S. For 1,805 of the 1,929 counties estimated to have at least one species with an RBL greater than two percent when air quality is meeting the current standard, only black cherry exceeds this level of RBL. If black cherry is excluded, the median RBL for the 10 remaining species decreases. For the median RBL values, 203 of the 239 counties estimated to have a median RBL above two percent when air quality is meeting the current standard are because of the presence of black cherry (U.S. EPA, 2014b, Table 6–7).

Additionally, the WREA estimated relative yield loss in timber production and associated changes in consumer and producer/farmer economic surplus using E–R functions for tree seedlings to calculate relative yield loss (equivalent to relative biomass loss) across full tree lifespans and through modeling of the resulting market-based welfare effects. Because the forestry and agriculture sectors are related and trade-offs occur between the sectors, the WREA calculated the resulting market-based welfare effects of O_3 exposure in the forestry and agriculture sectors on consumer and producer surplus.[206]

[205] The CASAC advised that the eastern cottonwood response data ''receive too much emphasis'' in a draft version of the PA, explaining that these ''results are from a gradient study that did not control for ozone and climatic conditions and show extreme sensitivity to ozone compared to other studies'' and that ''[a]lthough they are important results, they are not as strong as those from other experiments that developed E–R functions based on controlled ozone exposure'' (Frey, 2014b, p. 10).

[206] The WREA used the Forest and Agricultural Sector Optimization Model with Greenhouse Gases (FASOMGHG). FASOMGHG is a national-scale model that provides a complete representation of the impacts of meeting alternative standards on the U.S. forest and agricultural sectors. FASOMGHG simulates the allocation of land over time to competing activities in both the forest and agricultural sectors. FASOMGHG results include multi-period, multi-commodity results over 60 to

Because demand for most forestry and agricultural commodities is not highly responsive to changes in price, producer surplus (*i.e.,* producer gains) often declines. These declines can be more than offset by changes in consumer surplus gains from lower prices, but, in some cases, lower prices reduce producer gains more than can be offset by consumer surplus (U.S. EPA, 2014b, Appendix 6B, Table and B–9).

- In the current standard scenario, estimates of the relative yield loss for timber production are below one percent other than in the Southwest, Southeast, Central, and South regions (U.S. EPA, 2014b, section 6.3, Table 6–9) (see U.S. EPA, 2014b, Table 6–8 for clarification on region names). The highest yield loss occurs in upland hardwood forests in the South Central and Southeast regions at over three percent per year and in Corn Belt hardwoods at just over two percent loss per year (U.S. EPA, 2014b, section 6.3, Table 6–9).
- For the 15 and 11 ppm-hrs scenarios, relative yield loss estimates for timber production are above one percent in parts of the Southeast, Central, and South regions and above two percent in parts of the Southeast and Central U.S.
- For the 7 ppm-hrs scenario, relative yield loss estimates for timber production are above one percent in the Southeast and South regions (U.S. EPA, 2014b, section 6.3, Table 6–9).

The WREA also estimated impacts on tree growth and two ecosystem services provided by urban trees: removal of air pollutants and carbon storage. The estimates of the tons of carbon monoxide, nitrogen dioxide, ozone and sulfur dioxide removed are for a 25-year period in five urban case study areas: Baltimore, Syracuse, the Chicago region, Atlanta, and the urban areas of Tennessee (U.S. EPA, 2014b, section 6.7).[207]

- Estimates for all five urban case study areas indicate increased pollutant removal of O_3, nitrogen dioxide, carbon monoxide, and sulfur dioxide in the current standard scenario (U.S. EPA, 2014b, sections 6.7). The results for the 15 ppm-hrs scenario were very similar to those for meeting the current standard. For the 11 and 7 ppm-hrs scenarios, all five case study areas indicate smaller additional increases in air pollutant removal beyond moving from current conditions to the current standard (U.S. EPA, 2014b, sections 6.7).

The WREA estimated carbon storage related to O_3-induced biomass loss in forests and agricultural crops nationally and also in forests in five urban areas using the FASOMGHG and i-Tree models noted above (U.S. EPA, 2014b, section 6.6). Ozone effects on tree growth affects the climate regulation service provided by ecosystems by reducing carbon sequestration and storage (U.S. EPA, 2013a, section 9.4.3.4; U.S. EPA, 2014b, chapter 6, section 6.6). Because O_3 exposure affects photosynthesis and CO_2 uptake by trees, forests sequester less carbon and thus more carbon stays in the atmosphere. In the model used to calculate national-level impacts to forests and agriculture from O_3-related biomass loss, carbon sequestration reflects carbon in standing (live and dead) trees, forest soils, the forest understory vegetation, forest floor including litter and large woody debris, and wood products both in use and in landfills (U.S. EPA, 2014b, chapter 6, Appendix 6B, section 2.7.1).

- Over 30 years for the national-scale analysis, carbon storage in the forestry sector estimated for the current standard scenario is just over 89,000 million metric tons of CO_2 equivalents ($MMtCO_2e$); this is 11,840 more $MMtCO_2e$ storage associated with the reduced O_3-related growth impact from meeting the current standard as compared with recent conditions.[208] The estimates of carbon storage in the agricultural sector are much smaller (*i.e.,* 8,469 $MMtCO_2e$ for the current standard scenario which is 606 $MMtCO_2e$ more than the recent conditions scenario) (U.S. EPA, 2014b, section 6.6.1 and Appendix 6B). The forestry sector carbon storage estimated for each of the three W126 scenarios is just slightly greater than that estimated for the current standard. As a percentage of the current standard estimate, the three scenario estimates are less than 0.1% (13 $MMtCO_2e$), just under 1% (593 $MMtCO_2e$) and under 2% (1,600 $MMtCO_2e$) for the 15, 11 and 7 ppm-hrs scenarios, respectively (U.S. EPA, 2014b, Tables 6–19 and B–10).
- Estimates of the effects of avoided O_3-related biomass loss on carbon sequestration in forests in the five urban area case studies indicate the potential for an increase in carbon sequestration of somewhat more than one $MMtCO_2e$ for the current standard scenario compared to the recent conditions estimate (U.S. EPA, 2014b, section 6.6.2 and Appendix 6D). The additional increases in O_3-related carbon sequestration estimated across the five case studies for the three W126 scenarios are relatively small (U.S. EPA, 2014b, section 6.6.2 and Appendix 6D).

Although not discussed in detail here, the WREA also describes qualitative assessments for some ecosystem services that may be affected by O_3 effects on tree growth and productivity, such as commercial non-timber forest products and recreation (U.S. EPA, 2014b, section 6.4), aesthetic and non-use values (U.S. EPA, 2014b, section 6.4), increased susceptibility to insect attack and fire damage (U.S. EPA, 2014b, sections 5.3 and 5.4, respectively). Other ecological effects that are causally or likely causally associated with O_3 exposure, such as effects on terrestrial productivity, the water cycle, the biogeochemical cycle, and community composition (U.S. EPA, 2013a, Table 9–19), were not quantitatively addressed in the WREA due to a lack of sufficient quantitative information.

b. Key Uncertainties

The WREA identified several key limitations and uncertainties in the biomass loss assessments for trees, which may have a large impact on both overall confidence and confidence in individual analyses. Key uncertainties that affect the assessment of impacts on ecosystem services at the national and case-study scales, as well as across species, U.S. geographic regions and future years, include those associated with the interpolated and adjusted O_3 concentrations used to estimate W126 exposures in the air quality scenarios, the available seedling E–R functions, combining effects across sensitive species, the effects of compounding over time, and modeling impacts of biomass loss on timber harvesting and urban air pollutant removal.

With regard to the robust seedling E–R functions, the WREA provided some characterization of the variability of individual study results and the impact of that on estimates of W126 index values that might elicit different percentages of biomass loss in tree seedlings (U.S. EPA, 2014b, section 6.2.1.2). Even though the evidence shows that there are additional species affected by O_3-related biomass loss, the WREA only has E–R functions available to quantify this loss for 12 tree species. This limited information only allows a partial characterization of the O_3-related biomass loss impacts in trees associated

100 years in 5-year time intervals when running the combined forest-agriculture version of the model.

[207] The WREA used the i-Tree model for the urban case studies. i-Tree is a peer-reviewed suite of software tools provided by USFS.

[208] One $MMtCO_2e$ is equivalent to 208,000 passenger vehicles or the electricity to run 138,000 homes for 1 year as calculated by the EPA Greenhouse Gas Equivalencies Calculator (updated September 2013 and available at *http://www.epa.gov/cleanenergy/energy-resources/calculator.html*).

with recent O_3 index values and with just meeting the existing and potential alternative secondary standards. In addition, there are uncertainties inherent in these E–R functions, including the extrapolation of relative biomass loss rates from tree seedlings to adult trees and information regarding within-species variability. The overall confidence in the E–R function varies by species based on the number of studies available for that species. Some species have low within-species variability (*e.g.,* many agricultural crops) and high seedling/adult comparability (*e.g.,* aspen), while other species do not (*e.g.,* black cherry). The uncertainties in the E–R functions for biomass loss and in the air quality analyses are propagated into the analysis of the impact of biomass loss on ecosystem services, including provisioning and regulating services (U.S. EPA, 2014b, Table 6–27). The WREA characterizes the direction of potential influence of E–R function uncertainty as unknown, yet its magnitude as high, concluding that further studies are needed to determine how accurately the assessed species reflect the larger suite of O_3-sensitive tree species in the U.S. (U.S. EPA, 2014b, Table 6–27).

Another uncertainty associated with interpretation of the WREA biomass loss-related estimates concerns the potential for underestimation of compounding of growth effects across multiple years of varying concentrations. Though tree biomass loss impacts were estimated using air quality scenarios of three-year average W126 index values, the WREA also conducted an analysis to compare the impact of using a variable compounding rate based on yearly variations in W126 exposures to that of using a W126 index value averaged across three years. The WREA compared the compounded values for an example species occurring in the eastern U.S. and another example species occurring in the western U.S. In both examples, one species (tulip polar and ponderosa pine, respectively) and one climate region where that species occurred (Southeast and Southwest regions, respectively) were chosen and air quality values associated with just meeting the existing standard of 75 ppb were used. Within each region, the WREA analysis used both the W126 index value at each monitor in the region for each year and the three-year average W126 index value using the method described in Chapter 4 of the WREA. The results show that the use of the three-year average W126 index value may underestimate RBL values slightly (U.S. EPA, 2014b, section 6.2.1.4 and Figure 6–14). In both regions, the three-year average W126 index value is sometimes above and sometimes below the individual year W126 index value.

The WREA recognizes uncertainty regarding the extent to which the subset of studied tree species encompass the O_3 sensitive species in the U.S. and the extent to which it represents U.S. vegetation as a whole (U.S. EPA, 2013a, pp. 9–123 to 9–125; U.S. EPA, 2014b, Table 6–27). There are also uncertainties associated with estimating the national scale ecosystem-level impacts using wRBL. For example the wRBL estimates are likely biased low as there may be other unstudied O_3-sensitive tree species in some areas that are also being affected at those levels, although this analysis does not take into account the effects of competition, which could further affect forest biomass loss.

Uncertainties are recognized in the national-scale analyses of timber production, agricultural harvesting, and carbon sequestration, for which the WREA used the FASOMGHG model. These uncertainties include those associated with the functions for carbon sequestration, the assumptions made regarding proxy species where there are insufficient data, and the non-W126 E–R functions for three crops. The FASOMGHG model does not include agriculture and forestry on public lands, changes in exports due to O_3 into international trade projections, or forest adaptation. Despite the inherent limitations and uncertainties, the WREA concludes that the FASOMGHG model reflects reasonable and appropriate assumptions for a national-scale assessment of changes in the agricultural and forestry sectors due to changes in vegetation biomass associated with O_3 exposure (U.S. EPA, 2014b, sections 6.3, 6.5, 6.6, and 8.5.2, and Table 6–27).

In the case study analyses of five urban areas, the WREA used the i-Tree model, which includes an urban tree inventory for each area and species-specific pollution removal and carbon sequestration functions. However, i-Tree does not account for the potential additional VOC emissions from tree growth, which could contribute to O_3 formation. Uncertainties are also recognized with regard to the base inventory of city trees, the functions used for air pollutant removal and for carbon storage (U.S. EPA, 2014b, sections 6.6.2 and 6.7, and Table 6–27). Despite the inherent limitations and uncertainties, the WREA concludes that the i-Tree model reflects reasonable and appropriate assumptions for a case study assessment of pollution removal and carbon sequestration for changes in biomass associated with O_3 exposure (U.S. EPA, 2014b, sections 6.6.2, 6.7, and 8.5.2).

3. Crop Yield

Section IV.C.3.a below provides an overview of the assessments performed in the WREA to estimate the exposures and risks for crop yield, as well as the key results. Section IV.C.3.b summarizes the key uncertainties.

a. Overview and Summary of Key Results

The WREA conducted two analyses to estimate O_3 impacts related to crop yield, including annual yield losses estimated for 10 commodity crops grown in the U.S. with E–R functions and how these losses affect producer and consumer economic surpluses (U.S. EPA, 2014b, sections 6.2, 6.5). Summary estimates for crop yield loss related effects in the WREA are presented relative to a 5% yield loss benchmark based on consideration of CASAC's recommendation to consider a benchmark of 5% for median crop yield loss and to consider 5% yield loss for individual crop species. In addition, other benchmarks levels are considered in the WREA (*e.g.* 10% and 20%).

The WREA derived estimates of crop RYL estimates nationally and in a county-specific analysis. Crop-specific estimates of O_3-related RYL nationally were derived for each of the air quality scenarios from the 10 E–R functions for crops described above combined with information regarding crop distribution (U.S. EPA, 2014b, section 6.5). The WREA also reported crop RYL results at the county-level, as well as the number of crop-producing counties with greater than five percent RYL (U.S. EPA, 2014b, section 6.5.1, Appendix 6B).

- The largest reduction in O_3-induced crop yield loss and yield changes occurs when moving from the recent conditions scenario to the current standard scenario (U.S. EPA, 2014b, section 6.5). Among the major commercial crops, winter wheat and soybeans are more sensitive to ambient O_3 levels than other crops.
- In the current standard scenario, no counties have RYL estimates at or above 5% (U.S. EPA, 2014b, section 6.5).[209]

[209] In the air quality scenario for the current standard, a monitor that already met the current standard but was located within the same region as another monitor that was above the current standard would have had its concentration adjusted downward. This is due to the fact that concentrations were adjusted independently for each region, applying reductions to all monitors within the region, such that all monitors located within a region meet the standard (U.S. EPA, 2014b, section 4.3.4.2).

The WREA also estimated O_3-related crop impacts on producer and consumer surplus.[210] These are national-scale estimates of the effects of yield loss on agricultural harvesting, which supply provisioning services of food and fiber for each of the air quality scenarios. Overall effect on agricultural yields and producer and consumer surplus depends on (1) the ability of producers/farmers to substitute other crops that are less O_3 sensitive, and (2) the responsiveness, or elasticity, of demand and supply (U.S. EPA, 2014b, section 6.5).

- Estimates of consumer surplus, or consumer gains, were generally higher in the current standard scenario in the agricultural sector because higher productivity under lower O_3 concentrations increased total yields and reduced market prices (U.S. EPA, 2014b, Tables 6–17 and 6–18). Combined gains in producer and consumer surplus for forestry and agriculture were essentially unchanged for the 15 ppm-hrs scenario, but annualized gains increased by $21 million beyond the current standard scenario for the 11 ppm-hrs scenario and $231 million for the 7 ppm-hrs scenario. In some cases, lower prices reduce producer gains more than can be offset by higher yields (U.S. EPA, 2014b, Table 6–18).
- Because demand for most agricultural commodities is not highly responsive to changes in price, producer surplus or producer gains often declined. For agricultural welfare, annualized combined consumer and producer surplus gains were estimated to be $2.6 trillion in 2010 for the current standard scenario (U.S. EPA, 2014b, Table 6–17).

b. Key Uncertainties

The WREA discusses multiple areas of uncertainty associated with the crop yield loss estimates, including those associated with the model-based adjustment methodology as well as those associated with the projection of yield loss using the FASOMGHG model at the estimated O_3 concentrations (U.S. EPA, 2014b, Table 6–27, section 8.5). Because the W126 estimates generated in the air quality analyses are inputs to the vegetation risk analyses for crop yield loss, any uncertainties in the air quality analyses are propagated into the those analyses (U.S. EPA, 2014b, Table 6–27, section 8.5). Therefore, the air quality scenarios in the crop yield analyses have the same uncertainties and limitations as in the biomass loss analyses (summarized above), including those associated with the model-based adjustment methodology (U.S. EPA, 2014b, section 8.5).

4. Visible Foliar Injury

Section IV.C.4.a below provides an overview of the assessment in the WREA of O_3-related visible foliar injury and associated ecosystem services impacts, as well as the key results. Section IV.C.4.b summarizes the key uncertainties.

a. Overview and Summary of Key Results

The WREA presents a number of analyses of O_3-related visible foliar injury and associated ecosystem services impacts (U.S. EPA, 2014b, Chapter 7). An initial analysis using USFS FHM/FIA biosite data included the development of benchmark criteria reflecting different prevalences of visible foliar injury at different W126 exposures and soil moisture conditions. These criteria were then used in a screening-level characterization of the potential risk of foliar injury incidence in 214 national parks and a case study assessment of three national parks, which also provides limited characterization of the associated ecosystem services.

In the biosite data analysis, the WREA used the biomonitoring site data from the USFS FHM/FIA Network (USFS, 2011),[211] associated soil moisture data during the sample years, and national surfaces of ambient air O_3 concentrations based on spatial interpolation of monitoring data from 2006 to 2010 to calculate the proportion of biosites with any visible foliar injury. The proportion of biosites metric is derived by first ordering the data (across biosites and sample years) by W126 index value estimated for that biosite and year. Then for each W126 index value, the proportion of biosites is calculated with any foliar injury for all observations at or below that W126 index value. (U.S. EPA, 2014b, section 7.2). This analysis indicates that the proportion of biosites showing the presence of any foliar injury increases rapidly from zero to about 20 percent at relatively low W126 index values. Specifically: (1) the proportion of biosites exhibiting foliar injury rises rapidly with increasing W126 index values below approximately 10 ppm-hrs (W126 <10.46 ppm-hrs), and (2) there is relatively little change in this proportion with increasing W126 index values above approximately 10 ppm-hrs (W126 >10.46 ppm-hrs). The data for biosites during normal moisture years are very similar to the dataset as a whole, with an overall proportion of close to 18 percent for presence of any foliar injury. Among the biosites with a relatively wet season, the proportion of biosites showing injury is much higher and the relationship with annual W126 index value is much steeper. Much lower proportions of biosites show injury with relatively dry seasons (U.S. EPA, 2014b, section 7.2.3, Figures 7–10), consistent with the ISA finding that many studies have shown that dry periods tend to decrease the incidence and severity of O_3-induced visible foliar injury (U.S. EPA, 2013a, section 9.4.2). While these analyses indicate the potential for foliar injury to occur under conditions that meet the current standard, the extent of foliar injury that might be expected under such conditions is unclear from these analyses.

The national-scale screening-level assessment in 214 parks employed benchmark criteria developed from the above analysis.[212] [213] For example, annual O_3 concentrations corresponding to a W126 index value of 10.46 ppm-hrs represents the O_3 exposure concentration where the slope of exposure-response relationship changes for FHM biosites, with the percentage of biosites showing injury remaining relatively constant for higher W126 index values. The WREA refers to this as the ''base scenario'' benchmark. The

[210] Welfare economics focuses on the optimal allocation of resources and goods and how those allocations affect total social welfare. Total welfare is also referred to as economic surplus, which is the overall benefit a society, composed of consumers and producers, receives when a good or service is bought or sold, given a quantity provided and a market price. Economic surplus is divided into two parts: Consumer and producer surplus (U.S. EPA, 2014b, p. ES–6).

[211] Data were not available for several western states (Montana, Idaho, Wyoming, Nevada, Utah, Colorado, Arizona, New Mexico, Oklahoma, and portions of Texas).

[212] The parks assessed in the WREA include lands managed by the NPS in the continental U.S., which includes National Parks, Monuments, Seashores, Scenic Rivers, Historic Parks, Battlefields, Reservations, Recreation Areas, Memorials, Parkways, Military Parks, Preserves, and Scenic Trails.

[213] This analysis considered the approach in Kohut (2007), which assessed the risk of O_3-induced visible foliar injury on O_3 bioindicators (*i.e.,* O_3-sensitive vegetation) in 244 parks managed by the NPS. Consistent with advice from CASAC (Frey and Samet, 2012a), however, the WREA modified the approach used by Kohut (2007) to apply the W126 metric alone. The WREA applied different foliar injury benchmarks in this assessment after further investigation into the benchmarks applied in Kohut (2007), which were derived from biomass loss rather than visible foliar injury. Kohut cited a threshold of 5.9 ppm-hrs for highly sensitive species from Lefohn (1997), which was based on the lowest W126 estimate corresponding to a 10 percent growth loss for black cherry. For soil moisture, Kohut (2007) qualitatively assessed whether there appeared to be an inverse relationship between soil moisture and high O_3 exposure.

W126 benchmarks across this and the other four scenarios range from 3.05 ppm-hrs (foliar injury observed at five percent of biosites, normal moisture) up to 24.61 ppm-hrs (foliar injury observed at 10 percent of biosites, dry). For the scenario of 10 percent biosites with injury, W126 index values were approximately 4, 6, and 25 ppm-hrs for wet, normal and dry years, respectively. The national-scale screening-level assessment applied these benchmarks to 42 parks with O_3 monitors and a total of 214 parks with O_3 exposure estimated from the interpolated national O_3 surfaces for individual years from 2006 to 2010 (U.S. EPA, 2014b, Appendix 7A and section 7.3).

- Based on NPS lists, 95 percent of the 214 parks in this screening-level assessment contain at least one vegetation species sensitive to O_3-induced foliar injury (U.S. NPS, 2003, 2006).
- In the current standard scenario, none of the 214 parks had O_3 concentrations estimated to exceed the annual benchmark of a W126 index value above 10.46 ppm-hrs (U.S. EPA, 2014b, section 7.3.3.3).

The case study analyses focused on Great Smoky Mountains National Park (GRSM), Rocky Mountain National Park (ROMO), and Sequoia and Kings Canyon National Parks (SEKI). Information on visitation patterns, recreational activities and visitor expenditures was considered. For example, visitor spending in 2011 exceeded $800 million, $170 million and $97 million dollars in GRSM, ROMO and SEKI, respectively. In each park, the percent cover of species sensitive to foliar injury was estimated and the overlap between recreation areas within the park and elevated W126 concentrations was described. (U.S. EPA, 2014b, section 7.4).

- In the current standard scenario, the three-year average W126 index values were at or below 7 ppm-hrs in all areas of two of the three parks (GRSM and SEKI). Three-year average W126 index values were below 7 ppm-hrs in a little more than half of the area of the third park (ROMO) and between 7 and 11 ppm-hrs in the remainder of the park (U.S. EPA, 2014b, section 7.4).
- For the 15, 11 and 7 ppm-hrs scenarios, all areas of the three specific national parks evaluated (GRSM, SEKI, and ROMO) had three-year average W126 index values at or below 7 ppm-hrs, well below the 10.46 ppm-hrs benchmark. However, the extent of foliar injury that might be expected under these scenarios is unclear from these analyses.

Although not discussed in detail here, the WREA also describes qualitative assessments for some of the ecosystem services most likely to be affected by O_3-induced foliar injury such as cultural services, including aesthetic value and outdoor recreation. Aesthetic value and outdoor recreation depend on the perceived scenic beauty of the environment. Many outdoor recreation activities directly depend on the scenic value of the area, in particular scenic viewing, wildlife-watching, hiking, and camping. These activities and services are of significant importance to public welfare as they are enjoyed by millions of Americans every year and generate millions of dollars in economic value (U.S. EPA, 2014b, Chapters 5 and 7). Although data are not available to explicitly quantify O_3 effects on ecosystem services, the WREA includes several qualitative analyses.

b. Key Uncertainties

Uncertainties associated with these analyses are discussed in the WREA, sections 7.5 and 8.5.3, and in WREA Table 7–24, and also summarized in the PA (*e.g.,* U.S. EPA, 2014c, section 6.3). As discussed in the WREA (section 8.5.3), evaluating soil moisture is more subjective than evaluating O_3 exposure because of its high spatial and temporal variability within the O_3 season, and there is considerable subjectivity in the categorization of relative drought. The WREA generally concludes that the spatial and temporal resolution for the soil moisture data is likely to underestimate the potential for foliar injury to occur in some areas. In addition, there is lack of a clear threshold for drought below which visible foliar injury would not occur. In general, low soil moisture reduces the potential for foliar injury, but injury could still occur, and the degree of drought necessary to reduce potential injury is not clear. Studies in the ISA provide additional information regarding the role of soil moisture in influencing visible foliar injury response, (U.S. EPA, 2013a, section 9.4.2). These studies confirm that adequate soil moisture creates an environment conducive to greater visible foliar injury in the presence of O_3 than drier conditions. As stated in the ISA, ''[a] major modifying factor for O_3-induced visible foliar injury is the amount of soil moisture available to a plant during the year that the visible foliar injury is being assessed . . . because lack of soil moisture generally decreases stomatal conductance of plants and, therefore, limits the amount of O_3 entering the leaf that can cause injury'' (U.S. EPA, 2013a, p. 9–39). As a result, ''many studies have shown that dry periods in local areas tend to decrease the incidence and severity of O_3-induced visible foliar injury; therefore, the incidence of visible foliar injury is not always higher in years and areas with higher O_3, especially with co-occurring drought (Smith, 2012; Smith et al., 2003)'' (U.S. EPA, 2013a, p. 9–39). This ''. . . partial 'protection' against the effects of O_3 afforded by drought has been observed in field experiments (Low et al., 2006) and modeled in computer simulations (Broadmeadow and Jackson, 2000)'' (U.S. EPA, 2013a, p. 9–87). In considering the extent of any protective role of drought conditions, however, the ISA also notes that other studies have shown that ''drought may exacerbate the effects of O_3 on plants (Pollastrini et al., 2010; Grulke et al., 2003)'' and that ''[t]here is also some evidence that O_3 can predispose plants to drought stress (Maier-Maercker, 1998)''. Accordingly, the ISA concludes that ''the nature of the response is largely species-specific and will depend to some extent upon the sequence in which the stressors occur'' (U.S. EPA, 2013a, p. 9–87).

Due to the absence of biosite injury data in the Southwest region and limited biosite data in the West and West North Central regions, the W126 benchmarks for foliar injury that the WREA developed and applied in the national park screening assessment may not be applicable to these regions. The WREA applied the benchmarks from the national-scale analysis to a screening-level assessment of 214 national parks and case studies of three national parks. Therefore, uncertainties in the foliar injury benchmarks are propagated into these analyses.

Other uncertainties associated with these analyses include uncertainty associated with our understanding of the number and sensitivity of O_3 sensitive species, uncertainties associated with spatial assignment of foliar injury biosite data to 12 km × 12 km grid cells, and uncertainties associated with O_3 exposure data of vegetation and recreational areas within parks (U.S. EPA, 2014b, Table 7–22).

There are also important uncertainties in the estimated O_3 concentrations for the different air quality scenarios evaluated (U.S. EPA, 2014b, section 8.5), as discussed earlier in this section. These uncertainties only apply to the national park case studies because these are the only foliar injury analyses that rely on the air quality scenarios, but any uncertainties in the air quality analyses are propagated into those analyses. The WREA identifies additional uncertainties that are associated with

the national park case studies. Specifically, there is uncertainty inherent in survey estimates of participation rates, visitor spending/economic impacts, and willingness-to-pay. These surveys potentially double-count impacts based on the allocation of expenditures across activities but also potentially exclude other activities with economic value. In general, the national level surveys apply standard approaches, which minimize potential bias. Other sources of uncertainty are associated with the mapping, including park boundaries, vegetation species cover, and park amenities, such as scenic overlooks and trails. In general, the WREA concludes that there is high confidence in the park mapping (U.S. EPA, 2014b, Table 7–24).

D. Conclusions on Adequacy of the Current Secondary Standard

The initial issue to be addressed in the current review of the secondary O_3 standard is whether, in view of the currently available scientific evidence, exposure and risk information and air quality analyses, discussed in the PA, the existing standard should be revised. In drawing conclusions on adequacy of the current O_3 secondary standard, the Administrator has taken into account both evidence-based and quantitative exposure- and risk-based considerations, and advice from CASAC. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence from experimental and field studies evaluating welfare effects related to O_3 exposure, with a focus on policy-relevant considerations, as discussed in the PA. Air quality analyses inform these considerations with regard to cumulative, seasonal exposures occurring in areas of the U.S. that meet the current standard. Exposure- and risk-based considerations draw upon EPA assessments of risk of key welfare effects, including O_3 effects on forest growth, productivity, carbon storage, crop yield and visible foliar injury, expected to occur in model-based scenarios for the current standard, with appropriate consideration of associated uncertainties.

The following sections describe consideration of the evidence and the exposure/risk information in the PA and advice received from CASAC, as well as the comments received from various parties, and the Administrator's proposed conclusions regarding the adequacy of the current secondary standard.

1. Evidence- and Exposure/Risk-Based Considerations in the Policy Assessment

Staff assessments in the PA focus on the policy-relevant aspects of the assessment and integrative synthesis of the currently available welfare effects evidence in the ISA, analyses of air quality relationships with exposure metrics of interest, the exposure and risk assessments in the WREA, comments and advice of CASAC and public comment on drafts of the PA, ISA and WREA. The PA describes evidence- and exposure/risk-based considerations and presents staff conclusions for the Administrator to consider in reaching her proposed decision on the current standard. The focus of the initial PA conclusions is consideration of the question: Does the currently available scientific evidence and exposure/risk information, as reflected in the ISA and WREA, support or call into question the adequacy and/or appropriateness of the protection afforded by the current secondary O_3 standard?

The PA's general approach to informing judgments by the Administrator recognizes that the available welfare effects evidence demonstrates a range of O_3 sensitivity across studied plant species and documents an array of O_3-induced effects that extend from lower to higher levels of biological organization. These effects range from those affecting cell processes and individual plant leaves to effects on the physiology of whole plants, as well as the range from species effects and effects on plant communities to effects on related ecosystem processes and services. Given this evidence, the PA notes that it is not possible to generalize across all studied species regarding which cumulative exposures are of greatest concern, as this can vary by situation due to differences in exposed species sensitivity, the importance of the observed or predicted O_3-induced effect, the role that the species plays in the ecosystem, the intended use of the affected species and its associated ecosystem and services, the presence of other co-occurring predisposing or mitigating factors, and associated uncertainties and limitations. Therefore, in developing conclusions in the PA, staff takes note of the complexity of judgments to be made by the Administrator regarding the adversity of known and anticipated effects to the public welfare and are mindful that the Administrator's ultimate judgments on the secondary standard will most appropriately reflect an interpretation of the available scientific evidence and exposure/risk information that neither overstates nor understates the strengths and limitations of that evidence and information (U.S. EPA, 2014c, section 5.7).

In considering the estimates of exposures and risks for air quality scenarios assessed in the WREA, the PA: (1) Evaluates the weight of the scientific evidence concerning vegetation effects associated with those O_3 exposures; (2) considers the importance, from a public welfare perspective, of the O_3-induced effects on sensitive vegetation and associated ecosystem services that are known or anticipated to occur as a result of exposures in the assessed air quality scenarios; and, (3) recognizes that predictions of effects associated with any given O_3 exposure may be mitigated or exacerbated by actual conditions in the environment (*i.e.,* co-occurring modifying environmental and genetic factors). When considering WREA analyses that involve discrete exposure levels or varying levels of severity of effects, the PA's approach recognizes that the available welfare effects evidence demonstrates a wide range in O_3 sensitivities across studied plant species. The PA additionally considers the uncertainties associated with this information.

As an initial matter, the PA recognizes that the CAA does not require that a secondary standard be protective of all effects associated with a pollutant in the ambient air, but rather those considered adverse to the public welfare (as described in section IV.B.2 above). In considering the extent to which it may be appropriate to consider particular welfare effects adverse, the PA applies a paradigm used in past reviews. As discussed in section IV.B.2 above, this paradigm recognizes that the significance to the public welfare of O_3-induced effects on sensitive vegetation growing within the U.S. can vary depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Accordingly, any given O_3-related effect on vegetation and ecosystems (*e.g.,* biomass loss, crop yield loss, visible foliar injury) may be judged to have a different degree of impact on the public welfare depending, for example, on whether that effect occurs in a Class I area, a city park, or commercial cropland. In the last review, the Administrator took note of actions taken by Congress to establish public lands that are set aside for specific uses that are intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation

and wildlife within such areas for the enjoyment of future generations (73 FR 16497, March 27, 2008). Such public lands that are protected areas of national interest include national parks and forests, wildlife refuges, and wilderness areas (73 FR 16497, March 27, 2008). The PA notes that effects occurring in such areas would likely have the highest potential for being classified as adverse to the public welfare, given the expectation of preserving these areas to ensure their intended use is met (U.S. EPA, 2014c, section 5.1). In considering uses of vegetation and forested lands, the paradigm also includes consideration of impacts to ecosystem goods and services. In summary, the paradigm considered in the PA, consistent with the discussion in section IV.B.2 above, integrates the concepts of: (1) Variability in public welfare significance given intended use and value of the affected entity, such as individual species; (2) relevance of associated ecosystem services to public welfare; and (3) variability in spatial, temporal, and social distribution of ecosystem services associated with known and anticipated welfare effects. Further, the PA recognizes that there is no bright-line rule delineating the set of conditions or scales at which known or anticipated effects become adverse to public welfare.

With respect to the scientific evidence, the PA takes note of the longstanding evidence base that demonstrates O_3-induced effects that occur across a range of biological and ecological scales of organization, as described in the ISA and summarized in section IV.B.1 above (U.S. EPA, 2013a, p. 1–8). Many of the recent studies evaluated in this review have focused on and further increased our understanding of the molecular, biochemical and physiological mechanisms that explain how plants are affected by O_3 in the absence of other stressors (U.S. EPA, 2013a, section 9.3). These recent studies, in combination with the extensive and long-standing evidence, have further strengthened the coherence and consistency of the entire body of research since the last review. Consistent with conclusions in the 2006 AQCD, the ISA determined that a causal relationship exists between O_3 exposure and visible foliar injury on sensitive vegetation, reduced plant growth, reduced productivity in terrestrial ecosystems, reduced yield and quality of agricultural crops and alteration of below-ground biogeochemical cycles (U.S. EPA, 2013a, Table 1–2 and section 2.6). The relationship between O_3 exposures and reduced carbon sequestration in terrestrial ecosystems, alteration of terrestrial ecosystem water cycling and alteration of terrestrial community composition was concluded to be likely causal (U.S. EPA, 2013a, Table 1–2).

The PA recognizes that consistent with conclusions drawn in the last review, the currently available evidence base also strongly supports that effects on vegetation are attributable to cumulative seasonal O_3 exposures. Moreover, on the basis of the entire body of evidence in this regard, the ISA concludes that ''quantifying exposure with indices that cumulate hourly O_3 concentrations and preferentially weight the higher concentrations improves the explanatory power of exposure/response models for growth and yield, over using indices based on mean and peak exposure values'' (U.S. EPA, 2013a, p. 2–44). Accordingly, as in other recent reviews, the evidence continues to provide a strong basis for concluding that it is appropriate to judge impacts of O_3 on vegetation, related effects and services, and the level of public welfare protection achieved, using a cumulative, seasonal exposure metric, such as the W126-based metric. In this review, as in the last review, the CASAC concurs with this conclusion (Frey, 2014c, p. iii). Thus, based on the consistent and well-established evidence described above, the PA concludes that the most appropriate and biologically relevant way to relate O_3 exposure to plant growth, and to determine what would be adequate protection for public welfare effects attributable to the presence of O_3 in the ambient air is to characterize exposures in terms of a cumulative seasonal form, and in particular the W126 metric.

In considering the current standard with regard to protection from the array of O_3-related effects recognized in this review, the PA first considers effects related to forest tree growth, productivity and carbon storage, effects for which the ISA concludes the evidence supports a causal or likely causal relationship with exposures to O_3 in ambient air (U.S. EPA, 2014c, sections 5.2 and 5.7). In so doing, the PA notes that while changes in biomass affect individual tree species, the overall effect on forest ecosystem productivity depends on the composition of forest stands and the relative sensitivity of trees within those stands. In considering the evidence for these effects and the extent to which they might be expected to occur under conditions that meet the current secondary standard, the PA focused particularly on RBL estimates for the 11 species for which robust E–R functions have been developed. The PA recognized that recent studies, such as multiple-year exposures of aspen and birch, have provided additional evidence on tree biomass or growth effects associated with multiple year exposures in the field, including the potential for cumulative and carry-over effects. For example, findings from these studies indicate that effects of O_3 on birch seeds (reduced weight, germination, and starch levels) could lead to a negative impact on species regeneration in subsequent years and may have the potential to alter carbon metabolism of overwintering buds, potentially affecting growth in the following year. Other studies have reported that multiple-year exposures reduced tree size parameters in an aspen community, and increased the rate of conversion from a mixed aspen-birch community to a community dominated by the more tolerant birch, such that elevated O_3 may alter intra- and inter-species competition within a forest stand (U.S. EPA, 2013a, section 9.4.3; U.S. EPA, 2014c, section 5.2). In giving particular attention to tree seedling biomass loss estimates, the PA notes that CASAC ''concurs that biomass loss in trees is a relevant surrogate for damage to tree growth that affects ecosystem services such as habitat provision for wildlife, carbon storage, provision of food and fiber, and pollution removal'' (Frey, 2014c, p. 10).

In evaluating the current evidence and exposure/risk information associated with tree growth, productivity and carbon storage, with regard to the adequacy of public welfare protection afforded by the current standard, the PA considers the evidence of vegetation and welfare impacts in areas of the U.S. likely to have met the current standard. With regard to O_3 effects on tree growth, productivity and carbon storage and associated ecosystems and services, the PA focuses on relative biomass loss estimates based on the OTC-based E–R functions, noting that analyses newly performed in this review have reduced the uncertainty associated with using OTC E–R functions to predict tree growth effects in the field (U.S. EPA, 2014c, section 5.2.1; U.S. EPA, 2013a, section 9.6.3.2).

In focusing on RBL estimates, the PA recognized that comparison to an array of benchmarks would be informative to considerations of significance to public welfare. Included in this array were RBL values of 2% and 6% given emphasis by CASAC (Frey, 2014c). In considering the RBL estimates for different O_3 conditions associated with the current standard, the PA focused first on the median of the species-specific (composite) E–R functions. In so doing,

the PA takes note of CASAC's comments that a 6% median RBL is ''unacceptably high'', and that the 2% median RBL is an important benchmark to consider (Frey, 2014c).[214] Based on the summary of RBL estimates in the PA, the PA notes that the median species RBL estimate is at or below 2% for W126 exposure index values less than or equal to 7 ppm-hrs (U.S. EPA, 2014c, Table 6–1 and Appendix 5C). The median species RBL is at or above 6% for W126 index values of 19 ppm-hrs and higher.

In recognition of the significance of welfare effects in Class I areas, the PA gives appreciable weight to consideration of the occurrence of O_3 concentrations associated with the potential for RBL estimates above benchmarks of interest in Class I areas that meet the current standard. Based on air quality data for the period from 1998 to 2012, the PA focused consideration on 22 Class I areas, in which during one or more three-year periods the air quality met the current standard and the three-year average W126 index value was at or above 15 ppm-hrs (see Table 7 below, drawn from U.S. EPA, 2014c, Table 5–2). Across these 22 Class I areas, the highest single-year W126 index values for these three-year periods ranged from 17.4 to 29.0 ppm-hrs. In 20 of the areas, distributed across eight states (AZ, CA, CO, KY, NM, SD, UT, WY) and four regions (West, Southwest, West North Central and Central), this range was 19.1 to 29.0 ppm-hrs, exposure values for which the corresponding median species RBL estimates equal or exceed 6%, which CASAC has termed ''unacceptably high''. Recognizing that in any given year, other environmental factors can influence the extent to which O_3 may have the impact predicted by the E–R functions, the PA looked beyond single year occurrences of such magnitudes of W126 index values. For example, focusing on the highest three-year periods that include these highest annual values for 21 areas, the PA notes that in 10 areas (across five states in the West and Southwest regions), the three-year average W126 values (for the highest three-year period that includes these annual values) are at or above 19 ppm-hrs, ranging up to 22.5 ppm-hrs (for which the median species RBL estimate is above 7%). This indicates that the W126 value above 19 ppm-hrs is not simply a single year in a period of lower years, but that in these cases there were sustained higher values that contributed to a three-year W126 also above 19 ppm-hrs. In terms of the highest three-year values observed (regardless of single-year values), the PA additionally notes that the highest three-year average W126 index value (during periods meeting the current standard) was at or above 19 (ranging up to 22.5 ppm-hrs) in 11 areas, distributed among five states in the West and Southwest regions (U.S. EPA, 2014c, Table 5–2, Appendix 5B).

TABLE 7—O_3 CONCENTRATIONS IN CLASS I AREAS DURING PERIOD FROM 1998 TO 2012 THAT MET THE CURRENT STANDARD AND WHERE THREE-YEAR AVERAGE W126 INDEX VALUE WAS AT OR ABOVE 15 PPM-HRS

Class I Area	State/county	Design value (ppb)*	3-year Average W126 (ppm-hrs)* (# ≥19 ppm-hrs, range)	Annual W126 (ppm-hrs)* (# ≥19 ppm-hrs, range)	Number of 3-year periods
Bandelier Wilderness Area QA, DF, PP.	NM/Sandoval	70–74	15.8–20.8 (2, 20.0–20.8)	12.1–25.3 (4, 19.2–25.3)	8
Bridger Wilderness Area QA, DF.	WY/Sublette	69–72	15.1–17.4	9.9–19.2 (1, 19.2)	5
Canyonlands National Park QA, DF, PP.	UT/San Juan	69–73	15.0–20.5 (2, 19.8–20.5)	9.9–24.8 (5, 19.3–24.8)	9
Carlsbad Caverns National Park PP.	NM/Eddy	69	15.0–15.3	8.6–26.7 (1, 26.7)	3
Chiricahua National Monument DF, PP.	AZ/Cochise	69–73	15.7–18.0	13.2–21.6 (2, 19.3–21.6)	7
Grand Canyon National Park QA, DF, PP.	AZ/Coconino	68–74	15.3–22.2 (7, 19.2–22.2)	11.3–26.7 (7, 19.8–26.7)	12
John Muir Wilderness Area QA, DF, PP.	CA/Inyo	71–72	16.5–18.6	10.1–25.8 (2, 23.9–25.8)	3
Lassen Volcanic National Park DF, PP.	CA/Shasta	75	15.3	13.6–18.7	1
Mammoth Cave National Park BC, C, LP, RM, SM, VP, YP.	KY/Edmonson	74	15.9	12.5–22.5 (1, 22.5)	1
Mesa Verde National Park DF	CO/Montezuma	67–73	15.5–21.0 (2, 19.0–21.0)	10.7–23.6 (4, 19.7–23.6)	10
Mokelumne Wilderness Area DF, PP.	CA/Amador	74	17.6	14.8–22.6 (1, 22.6)	1
Petrified Forest National Park.	AZ/Navajo	70	15.7	12.9–19.2 (1, 19.2)	1
Pinnacles National Monument.	CA/San Benito	74	15.1	13.1–17.4	1
Rocky Mountain National Park QA, DF, PP.	CO/Boulder	73–75	15.1–19.3 (1, 19.3)	9.5–25.1 (5, 20.7–25.1)	6
	CO/Larimer	74	15.0–18.3	8.1–25.8 (3, 19.1–25.8)	3
Saguaro National Park DF, PP	AZ/Pima	69–74	15.4–18.9	11.0–23.1 (3, 20.0–23.1)	6
Sierra Ancha Wilderness Area DF, PP.	AZ/Gila	72–75	17.9–22.4 (3, 20.2–22.4)	14.8–27.5 (4, 20.3–27.5)	4

[214] The CASAC provided several comments related to 2% RBL for tree seedlings both with regard to its use in summarizing WREA results and with regard to consideration of the potential significance of vegetation effects, as summarized in sections IV.D.2 and IV.E.3. In identifying 2% as an important benchmark, CASAC referenced the 1996 workshop sponsored by the Southern Oxidants Study group at which, as noted in section IV.B.2 above, participants identified annual percentages of tree seedling growth reduction and crop yield loss they considered important to their judgments on a secondary standard. The workshop report provides no explicit rationale for the percentages identified or specification with regard to number or proportion of species for which such percentages should be met (Heck and Cowling, 1997).

TABLE 7—O_3 CONCENTRATIONS IN CLASS I AREAS DURING PERIOD FROM 1998 TO 2012 THAT MET THE CURRENT STANDARD AND WHERE THREE-YEAR AVERAGE W126 INDEX VALUE WAS AT OR ABOVE 15 PPM-HRS—Continued

Class I Area	State/county	Design value (ppb)*	3-year Average W126 (ppm-hrs)* (# ≥19 ppm-hrs, range)	Annual W126 (ppm-hrs)* (# ≥19 ppm-hrs, range)	Number of 3-year periods
Superstition Wilderness Area PP.					
	AZ/Maricopa	75	22.4 (1, 22.4)	14.5–28.6 (2, 27.4–28.6)	1
	AZ/Pinal	73–75	18.7–22.5 (2, 20.8–22.5)	14.8–29.0 (3, 22.6–29.0)	3
Weminuche Wilderness Area QA, DF, PP.	CO/La Plata	70–74	15.0–19.1 (1, 19.1)	10.9–21.0 (2, 20.8–21.0)	5
West Elk Wilderness Area QA, DF.	CO/Gunnison	68–73	15.6–20.1 (1, 20.1)	12.9–23.9 (3, 21.1–23.9)	8
Wind Cave National Park QA, PP.	SD/Custer	70	15.4	12.2–20.6 (1, 20.6)	1
Yosemite National Park QA, DF, PP.	CA/Tuolumne ...	73–74	20.7–20.8 (2, 20.7–20.8)	19.7–22.1 (4, 19.7–22.1)	2
Zion National Park QA, DF, PP	UT/Washington	70–73	17.8–21.1 (2, 20.3–21.1)	14.9–24.2 (5, 19.3–24.2)	4

*Based on data from *http://www.epa.gov/ttn/airs/airsaqs/detaildata/downloadaqsdata.htm*. W126 values are truncated after first decimal place. Superscript letters refer to species present for which E–R functions have been developed. QA=Quaking Aspen, BC=Black Cherry, C=Cottonwood, DF=Douglas Fir, LP=Loblolly Pine, PP=Ponderosa Pine, RM=Red Maple, SM=Sugar Maple, VP=Virginia Pine, YP=Yellow (Tulip) Poplar. Sources include USDA–NRCS (2014,*http://plants.usda.gov*), USDA–FS (2014, *http://www.fs.fed.us/foresthealth/technology/nidrm2012.shtml*) UM–CFCWI (2014, *http://www.wilderness.net/printFactSheet.cfm?WID=583*) and Phillips and Comus (2000).

In considering the data analysis for 22 Class I areas described above, the PA additionally considers the species-specific RBL estimates for quaking aspen and ponderosa pine, two tree species that are found in many of these 22 areas and have a sensitivity to O_3 exposure that places them near the middle of the group for which E–R functions have been established (U.S. EPA, 2014c, sections 5.2 and 5.7). In the Class I areas where ponderosa pine is present, the highest single year W126 index values ranged from 18.7 to 29.0 ppm-hrs and the highest three-year average W126 values in which these single year values were represented ranged from 15 to 22.5 ppm-hrs, with these three-year values above 19 ppm-hrs in eight areas across five states. The ponderosa pine RBL estimates for 29 and 22.5 ppm-hrs are approximately 12% and 9%, respectively (U.S. EPA, 2014c, Appendix 5C). In Class I areas where quaking aspen is present, the highest single year W126 index values ranged from 19.2 to 26.7 ppm-hrs and the highest three-year average W126 values in which these single year values were represented ranged from 15.0 to 22.2 ppm-hrs, with these three-year values above 19 ppm-hrs in eight areas across five states. The quaking aspen RBL estimates for 26.7 and 22.2 ppm-hrs are approximately 16% and 13%, respectively (U.S. EPA, 2014c, Appendix 5C).

The PA describes the above observations, particularly in light of advice from CASAC, summarized in section IV.D.2 below, as evidence of the occurrence in Class I areas during periods where the current standard is met of cumulative seasonal O_3 exposures of a magnitude for which the tree growth impacts indicated by the estimated median species RBL might reasonably be concluded to be important to public welfare (U.S. EPA, 2014c, sections 5.2.1 and 5.7).

In considering the WREA analyses of effects on tree growth and associated ecosystem services in the air quality scenario for the current standard, the PA first takes note of the potential for the interpolation method used in creating the national surface of O_3 concentrations for the air quality scenarios to underestimate the higher W126 values such that W126-based exposures would be expected to be somewhat higher than those included in each scenario (U.S. EPA, 2014b, pp. 5–31 to 5–32). While recognizing this, the PA considers results of the WREA analyses for the current standard scenario and the 11 species of trees, for which robust E–R functions are available. These results indicate that O_3 can impact growth of these species across the U.S., as well as an array of associated ecosystem services provided by forests, including timber production, carbon storage and air pollution removal (U.S. EPA, 2014b, sections 6.2–6.8; U.S. EPA, 2014c, section 5.2).

With regard to WREA analyses of ecosystem services, the PA notes that the national-scale analysis of O_3 impacts on carbon storage indicates appreciably more storage in the air quality scenario for the current standard (approximately 11,000 $MMtCO_2e$, over 30 years) compared to the scenario for recent, higher O_3 conditions (U.S. EPA, 2014b, Appendix 6B, Table B–10). The PA additionally considers the WREA estimates of tree growth and ecosystem services provided by urban trees over a 25-year period for five urban areas based on case-study scale analyses that quantified the effects of biomass loss on carbon storage and pollution removal (U.S. EPA, 2014b, sections 6.6.2 and 6.7; U.S. EPA, 2014c, sections 5.2 and 5.7). The urban areas included in this analysis represent diverse geography in the Northeast, Southeast, and Central regions, although they do not include an urban area in the western U.S. Estimates of the effects of O_3-related biomass loss on carbon sequestration indicate the potential for an increase of somewhat more than a $MMtCO_2e$ for the current standard scenario as compared to the recent conditions scenario (U.S. EPA, 2014b, section 6.6.2 and Appendix 6D; U.S. EPA, 2014c, sections 5.2 and 5.7). The PA also notes the WREA estimates of increased pollution removal in the current standard scenario as compared to the scenario for recent conditions (U.S. EPA, 2014b, section 6.6.2; U.S. EPA, 2014c, section 5.2.2).

In considering the significance of these WREA analyses of risks for the associated ecosystem services for timber production, air pollution removal, and carbon sequestration, the PA takes note of the large uncertainties associated with these analyses (see U.S. EPA, 2014b, Table 6–27), and the potential for these findings to underestimate the response at the national scale. While noting the potential usefulness of considering predicted and anticipated impacts to these services in assessing the extent to which the current information supports or calls into question the adequacy of the protection afforded by the current standard, the PA also notes that staff places limited

weight on the absolute magnitude of the risk results for these ecosystem service endpoints due to the identification of significant associated uncertainties (U.S. EPA, 2014c, sections 5.2 and 5.7).

In reaching conclusions regarding support for the adequacy of the current secondary standard provided by the currently available information on O_3-induced effects on trees and associated services, the PA takes note of: (1) the robust evidence supporting the causal relationship between cumulative O_3 exposures and effects on tree growth and productivity, and information from model simulations supporting the determination of a likely causal relationships for carbon storage in terrestrial ecosystems (U.S. EPA, 2013a, sections 2.6.2.1 and 9.4.3); (2) the tree seedling E–R functions evidence, which has been strengthened and demonstrates variability in sensitivity to O_3 across species; (3) estimates of median species RBL at or above 6% associated with W126-based exposure levels in several areas when O_3 concentrations were at or below the current standard; (4) growth effects estimates associated with exposure concentrations in several Class I areas based on O_3 concentrations from 1998–2012 that were at or below the current standard; (5) evidence that impacts from single year exposures can carry over to the subsequent year and/or cumulate over multiple years with repeated annual exposures; (6) evidence from recent mechanistic studies and field based studies that support earlier findings from OTC studies; and (7) WREA analyses indicating that O_3-induced biomass loss can impact ecosystem services provided by forests, including timber production, carbon storage, and air pollution removal, even when air quality is adjusted to just meet the current standard. Given the above, and noting CASAC views (described in section IV.D.2 below), the PA concludes that the current evidence and exposure/risk information call into question the adequacy of public welfare protection afforded by the current standard from the known and anticipated adverse effects associated with O_3-induced impacts on tree growth, productivity and carbon storage, including the associated ecosystem services assessed in this review. Therefore, the PA concludes that it is appropriate to consider revision of the secondary standard to provide increased protection.

With respect to crops, the PA takes note of the extensive and long-standing evidence on the detrimental effect of O_3 on crop production, which continues to be confirmed by newly available evidence (U.S. EPA, 2013a, section 9.4.4; U.S. EPA, 2014c, sections 5.3 and 5.7). The PA additionally notes that recent studies have highlighted the effects of O_3 on crop quality, such as through decreases in the nutritive quality of grasses, and in the macro- and micro-nutrient concentrations in fruits and vegetable crops (U.S. EPA, 2013a, section 9.4.4; U.S. EPA, 2014c, section 5.3). Further, the PA notes that there has been little published evidence that crops are becoming more tolerant of O_3, taking note particularly of the ISA analyses of data from cultivars used in NCLAN studies, and yield data for modern cultivars from SoyFACE which confirm that the average response of soybean yield to O_3 exposure has not changed in current cultivars (U.S. EPA, 2006a; U.S. EPA, 2013a, section 9.6.3; U.S. EPA, 2014c, section 5.3). In consideration of the currently available evidence for O_3 effects on crops, the PA concludes that the recently available evidence, as assessed in the ISA, continues to support the conclusions of the 1996 and 2006 CDs that ambient O_3 concentrations can reduce the yield of major commodity crops in the U.S, and that the currently available evidence continues to support the use of the E–R functions developed for 10 crops from OTC experiment data. Further, the PA recognizes that important uncertainties have been reduced regarding the exposure-response functions for crop yield loss, especially for soybean, the second-most planted field crop in the U.S.,[215] with the ISA generally reporting consistent results across exposure techniques and across crop varieties (U.S. EPA, 2013a, section 9.6.3.2).

With regard to consideration of the quantitative impacts of O_3 on crop yield, the PA considers RYL estimates for O_3 conditions associated with the current standard. As in the case of the PA considerations of RBL estimates for tree seedlings, the PA recognized CASAC comments, which described greater than 5% RYL for the median crop species as ''unacceptably high'' and 5% RYL for the median crop species as adverse, while noting the opportunities to alter management of annual crops (Frey, 2014c, pp. iii and 14). The PA notes that staff analyses of recent monitoring data (2009–2011) indicate that O_3 concentrations in multiple agricultural areas in the U.S. that meet the current standard correspond to W126 index levels above 12 ppm-hrs, a value for which soybean RYL estimates are greater than 5%. In particular, the PA notes that while the design values for two counties in the Midwest met the current standard in 2009–2011, both had a maximum annual W126 of 19 ppm-hrs (in 2011) for which the soybean annual RYL estimate, based on the E–R function, is 9%.[216]

In considering the evidence and exposure/risk-based information for effects on crops, the PA notes the CASAC comments regarding the use of crop yields as a surrogate for consideration of public welfare impacts, in which it noted that ''[c]rops provide food and fiber services to humans'' and that ''[e]valuation of market-based welfare effects of O_3 exposure in forestry and agricultural sectors is an appropriate approach to take into account damage that is adverse to public welfare'' (Frey, 2014c, p. 10; U.S. EPA, 2014c, section 5.7). The PA additionally notes, however, as recognized in section IV.B.2 above that the determination of the point at which O_3-induced crop yield loss becomes adverse to the public welfare is still unclear, given that crops are heavily managed with additional inputs that have their own associated markets and that benefits can be unevenly distributed between producers and consumers. The PA further notes that to the extent protection is provided by the current standard with regard to impacts on trees, protection may also be provided for commodity crops (U.S. EPA, 2014c, sections 5.3 and 5.7).

In reaching conclusions regarding support provided for the adequacy of the current secondary standard by the currently available information on O_3-related crop effects, the PA notes: (1) the support for a causal relationship between cumulative O_3 exposures and effects on crop yields and quality (U.S. EPA, 2013a, section 9.4.4); (2) the evidence supporting E–R functions for 10 crops, which has been strengthened in this review and which demonstrates variability in sensitivity to O_3 across species; (3) evidence from recent mechanistic studies and field based studies supporting earlier findings from OTC studies; (4) evidence that crops, and in particular soybean, have not become more tolerant of O_3 (U.S. EPA, 2013a, section 9.6.3, 9.4.4.1); and, (5) WREA analysis results indicating that O_3-induced crop yield loss can impact producer and consumer surpluses and

[215] See *http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/background.aspx*

[216] The monitoring data reflect observations in locations that meet the current standard. The WREA analysis that assessed crop yield loss used a model-developed air quality scenario to reflect air quality associated with the current standard (as described in section IV.C.1 above). In so doing, adjustments are made to create air quality that meets the standard and when the highest monitor in an area is adjusted downward to meet the standard, concentrations at nearby monitors that already meet the standard are also reduced.

the interaction between agriculture and timber production.

With regard to visible foliar injury, the PA recognizes the long-standing evidence that has established that O_3 causes diagnostic visible injury symptoms on studied bioindicator species and that soil moisture is a major confounding effect that can decrease the incidence and severity of visible foliar injury under dry conditions and vice versa (U.S. EPA, 2014c, sections 5.4 and 5.7). As at the time of the last review, the most extensive dataset regarding visible foliar injury incidence across the U.S. is that collected by the U.S. Forest Service (USFS) Forest Health Monitoring/Forest Inventory and Analysis (FHM/FIA) Program, which has documented incidence of visible foliar injury in both the eastern and western U.S. Evidence available in the current review includes studies using controlled exposures as well as multi-year field surveys. In addition to supporting prior conclusions, the newly available studies also address some uncertainties identified in the last review, such as the influence of soil moisture on visible injury development (U.S. EPA, 2013a, section 9.4.2). As stated in the ISA, ''many studies have shown that dry periods in local areas tend to decrease the incidence and severity of O_3-induced visible foliar injury; therefore, the incidence of visible foliar injury is not always higher in years and areas with higher O_3, especially with co-occurring drought'' (U.S. EPA, 2013a, p. 9–39). The ISA additionally concludes, however, that ''the nature of the response is largely species-specific and will depend to some extent upon the sequence in which the stressors occur'' (U.S. EPA, 2013a, p. 9–87). As recognized in the PA, this area of uncertainty complicates characterization of the potential for visible foliar injury and its severity or extent of occurrence for any given air quality conditions and thus complicates identification of air quality conditions that might be expected to provide a specific level of protection from this effect (U.S. EPA, 2014c, sections 5.4 and 5.7).

Information available in this review indicates the occurrence of visible foliar injury in some Class I areas during times when O_3 concentrations met or would be expected to meet the current standard (U.S. EPA, 2014c, sections 5.4.1 and 5.7). In noting this occurrence in Class I areas, the PA notes it has particular public welfare significance in light of direction from Congress that these areas merit a high level of protection (U.S. EPA, 2014c, sections 5.1, 5.4.1 and 5.7). The PA also notes that visible foliar injury surveys are used by the federal land managers to assess potential O_3 impacts in Class I areas (USFS, NPS, FWS, 2010). Given this focus on visible foliar injury, the PA concludes that such O_3-induced impacts have the potential to impact the public welfare in scenic and/or recreational areas on an annual basis. Visible foliar injury is associated with important cultural and recreational ecosystem services to the public, such as scenic viewing, wildlife-watching, hiking, and camping, that are of significance to the public welfare and enjoyed by millions of Americans every year, generating millions of dollars in economic value (U.S. EPA, 2014b, section 7.1). In addition, several tribes have indicated that many of the O_3-sensitive species (including bioindicator species) are culturally significant (U.S. EPA, 2014c, Table 5–1). With respect to agricultural species, such visible effects of O_3 exposure can affect the market value of certain crops and ornamentals for which leaves are the product, such as spinach (U.S. EPA, 2006a, p. AX–9–189). The PA additionally notes CASAC comments that ''visible foliar injury can impact public welfare by damaging or impairing the intended use or service of a resource'', including through ''visible damage to ornamental or leafy crops that affects their economic value, yield, or usability; visible damage to plants with special cultural significance; and visible damage to species occurring in natural settings valued for scenic beauty or recreational appeal'' (Frey, 2014c, p. 10).

With regard to the exposure and risk-based information, the PA takes note of the WREA analyses of the nationwide dataset (2006–2010) for USFS/FHM biosites, including the observation that the proportion of biosites with injury varies with soil moisture conditions and O_3 W126 index values (U.S. EPA, 2014b, Chapter 7, Figure 7–10; U.S. EPA, 2014c, section 5.4.2). These analyses indicate that the proportion of biosites showing visible foliar injury incidence increases steeply with W126 index values up to approximately 10 ppm-hrs, with little difference in incidence across higher W126 index levels. The screening-level assessment of national parks indicated that risk of visible foliar injury is likely to be lower in most national parks after simulating just meeting the current standard, although visible foliar injury would likely continue to occur at lower O_3 exposures, including some sensitive species growing in National Parks and other Class I areas that may provide important cultural ecosystem services to the public. The PA also notes the WREA recognition that many of the outdoor recreational activities which directly depend on the scenic value of the area are of significant importance to public welfare as they are enjoyed by millions of Americans every year and generate millions of dollars in economic value (U.S. EPA, 2014b, Chapter 5, Chapter 7).

In reaching conclusions regarding support for the adequacy of the current secondary standard provided by the currently available information on O_3-induced visible foliar injury, the PA took note of: (1) The evidence for many species of native plants, including trees, that have been observed to have visible foliar injury symptoms in both OTC and field settings, some of which have also been identified as bioindicators of O_3 exposure by the USFS; (2) the finding that visible foliar injury incidence can occur at very low cumulative exposures, but due to confounding by soil moisture and other factors, it is difficult to predictively relate a given O_3 exposure to plant response; (3) information indicating the occurrence of visible foliar injury in some Class I areas under air quality conditions expected to meet the current standard; and, (4) WREA analyses, based on USFS biosite data, indicating a relationship of the proportion of biosites showing visible foliar injury incidence with W126 index values below approximately 10 ppm-hrs (U.S. EPA, 2014c, section 5.7).

The PA additionally recognizes a lack of guidance for federal land managers regarding what spatial scale or degree of severity of visible foliar injury is considered sufficient to trigger protective action for O_3 sensitive AQRVs. Further, there does not appear to be any consensus in the literature in this regard, and CASAC, while identifying benchmarks to consider for percent biomass loss and yield loss for tree seedlings and commodity crops, respectively, did not provide a similar recommendation for this endpoint. Likewise, as in previous reviews, the ISA notes the difficulty in relating visible foliar injury symptoms to other vegetation effects such as individual plant growth, stand growth, or ecosystem characteristics (U.S. EPA, 2013a, section 9.4.2, p. 9–39) and further notes that the full body of evidence indicates that there is wide variability in this endpoint, such that although evidence shows visible foliar injury can occur under very low cumulative O_3 concentrations, ''. . .the degree and extent of visible foliar injury development varies from year to year and site to site . . ., even among co-members of a population exposed to similar O_3 levels, due to the influence

of co-occurring environmental and genetic factors'' (U.S. EPA, 2013a, section 9.4.2, p. 9–38).

Given the above, and taking note of CASAC views, the PA recognizes visible foliar injury as an important O_3 effect which, depending on severity and spatial extent, may reasonably be concluded to be of public welfare significance, especially when occurring in nationally protected areas. While noting the uncertainties associated with describing the potential for visible foliar injury and its severity or extent of occurrence for any given air quality conditions, the PA notes the occurrence of O_3-induced visible foliar injury in areas, including federally protected Class I areas that meet the current standard, and suggests it may be appropriate to consider revising the standard to achieve greater protection, while recognizing that the degree to which O_3-induced visible foliar injury would be judged important and potentially adverse to public welfare is uncertain (U.S. EPA, 2014c, section 5.7).

With regard to other welfare effects, for which the ISA determined a causal or likely causal relationships with O_3 in ambient air, such as alteration of ecosystem water cycling and changes in climate, the PA concludes there are limitations in the available information which affect our ability to consider potential impacts of air quality conditions associated with the current standard.

In reaching conclusions on options for the Administrator's consideration, the PA indicates that the final decision to retain or revise the current secondary O_3 standard is a public welfare policy judgment to be made by the Administrator, based on her judgment as to what level of air quality would be requisite (*i.e.,* neither more nor less stringent than necessary) to protect the public welfare from any known or anticipated adverse effects. This final decision will draw upon the available scientific evidence for O_3-attributable welfare effects and on quantitative analyses of vegetation and ecosystem exposures and associated risks to vegetation, ecosystems and their associated services, and judgments about the appropriate weight to place on the range of uncertainties inherent in the evidence and analyses. In making this decision, the Administrator will need to weigh the importance of these effects and their associated ecosystem services in the overall context of public welfare protection.

Based on the considerations described in the PA and summarized here, the PA concludes that the currently available evidence and exposure/risk information call into question the adequacy of the public welfare protection provided by the current standard and provides support for considering potential alternative standards to achieve increased public welfare protection, especially for sensitive vegetation and ecosystems in federally protected Class I and similarly protected areas. In this conclusion, staff gives particular weight to the evidence indicating the occurrence in Class I areas that meet the current standard of cumulative seasonal O_3 exposures associated with estimates of tree growth impacts of a magnitude that may reasonably be considered important to public welfare.

2. CASAC Advice

Beyond the evidence- and exposure/risk-based considerations in the PA discussed above, the EPA's consideration of the adequacy of the current secondary standard also takes into account the advice and recommendations of CASAC.

In its advice offered in the current review, based on the updated scientific and technical record since the 2008 rulemaking, the CASAC stated that they ''support the conclusion in the Second Draft PA that the current secondary standard is not adequate to protect against current and anticipated welfare effects of ozone on vegetation'' (Frey, 2014c, p. iii) and that the PA ''clearly demonstrates that ozone-induced injury may occur in areas that meet the current standard'' (Frey, 2014c, p. 12). The Panel further stated ''[w]e support EPA's continued emphasis on Class I and other protected areas'' (Frey, 2014c, p. 9). Additionally, the CASAC indicated support for the concept of ecosystem services ''as part of the scope of characterizing damage that is adverse to public welfare'' and ''concurs that trees are important from a public welfare perspective because they provide valued services to humans, including aesthetic value, food, fiber, timber, other forest products, habitat, recreational opportunities, climate regulation, erosion control, air pollution removal, and hydrologic and fire regime stabilization'' (Frey, 2014c, p. 9). Similar to comments from CASAC in the last review, including comments on the proposed reconsideration, the current CASAC also endorsed the PA discussions and conclusions on biologically relevant exposure metrics and the focus on the W126 index accumulated over a 12-hour period (8am–8pm) over the three-month summation period of a year resulting in the maximum value (Frey, 2014c, p. iii).

In addition, CASAC stated that ''relative biomass loss for tree species, crop yield loss, and visible foliar injury are appropriate surrogates for a wide range of damage that is adverse to public welfare'' (Frey, 2014c, p. 10). With respect to relative biomass loss for tree species, CASAC states that it is appropriate to ''include levels that aim for not greater than 2% RBL for the median tree species'' and that a median tree species RBL of 6% is ''unacceptably high.'' With respect to crop yield loss, CASAC points to a benchmark of 5%, stating that a crop RYL for median species over 5% is ''unacceptably high'' (Frey, 2014c, p. 13).

3. Administrator's Proposed Conclusions on Adequacy of the Current Standard

In considering the adequacy of the current secondary O_3 standard, the Administrator has considered the assessment of the current evidence in the ISA, findings of the WREA, including associated limitations and uncertainties, considerations and staff conclusions and associated rationales presented in the PA, views expressed by CASAC, and public comments. In taking into account the information discussed above with regard to the nature of O_3-related effects on vegetation, the Administrator has taken particular note of: the PA analysis of the magnitude of tree seedling growth effects (biomass loss) estimated for different cumulative, seasonal, concentration-weighted exposures in terms of the W126 metric; the monitoring analysis in the PA of W126 exposures occurring in locations where the current standard is met, including those locations in Class I areas, and associated estimates of tree seedling growth effects; the analyses in the WREA illustrating the geographic distribution of tree species for which E–R functions are available and relative differences estimated for O_3-related growth impacts across areas of the U.S. for the air quality scenarios, taking into account the identified potential for the WREA's scenario for the current standard to underestimate the highest W126-based O_3 values that would be expected to occur.

As an initial matter, the Administrator recognizes the appropriateness and usefulness of the W126 metric, as described in sections IV.B.1 and IV.D.1 above, in evaluating O_3 exposures of potential concern for vegetation effects. In so doing, the Administrator additionally notes support conveyed by CASAC for such a use for this metric.

With regard to considering the adequacy of public welfare protection provided by the current secondary standard, the Administrator focuses first on welfare effects related to reduced

native plant growth and productivity in terrestrial ecosystems, taking note of the ISA conclusion of a causal relationship between O_3 in the ambient air and these effects. In considering the assessment of the information available in this review with regard to O_3 effects on vegetation growth and productivity, the Administrator takes note of the evidence from OTC studies of the effects of O_3 exposure on tree seedling growth that support robust E–R functions for 11 tree seedling species, and the characterization of growth effects across these species for different cumulative seasonal concentration-weighted exposures using the W126 metric. Reductions in growth of sensitive species, as recognized in section IV.B above, have the potential to result in effects on ecosystem productivity, as well as, on forest and forest community composition. The Administrator takes particular note of the evidence, described in section IV.D.1 above, of the occurrence in Class I areas during periods where the current standard is met of cumulative seasonal O_3 exposures for which median species RBL estimates are of a magnitude that CASAC has termed ''unacceptably high.'' In so doing, the Administrator also takes note of a number of actions taken by Congress to establish public lands that are set aside for specific uses intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation and wildlife within such areas for the enjoyment of future generations. Such public lands that are protected areas of national interest include national parks and forests, wildlife refuges, and wilderness areas (many of which have been designated Class I areas).[217]

While recognizing the variability in the various environmental factors that can influence the occurrence and severity of the effect of ambient O_3 concentrations on vegetation in different locations, the Administrator concludes that the information referenced above including the currently available, extensive evidence base and also factors affecting the significance of impacts to public welfare, as well as WREA estimates regarding the potential for occurrence of impacts important to public welfare, provides an appropriate basis to inform a conclusion as to whether the current standards provide adequate protection against O_3-related vegetation effects on public welfare. With regard to the results of the monitoring analysis, the Administrator takes note of the PA conclusions that the impacts on tree growth (and the potential for associated ecosystem effects) estimated for W126 values found to occur in Class I areas when meeting the current standard are reasonably concluded to be important from a public welfare standpoint in terms of both the magnitude of the vegetation effects and the significance to public welfare of such effects in such areas, calling into question the adequacy of the current secondary standard.

The Administrator also recognizes the causal relationships between O_3 in the ambient air and visible foliar injury, reduced yield and quality of agricultural crops and alteration of below-ground biogeochemical cycles associated with effects on growth and productivity. As to visible foliar injury, the Administrator takes note of the complexities and limitations in the evidence base regarding characterizing air quality conditions with respect to the magnitude and extent of risk for visible foliar injury. She additionally recognizes the challenges of associated judgments with regard to adversity of such effects to public welfare. In taking note of the conclusions with regard to crops, she recognizes the complexity of considering adverse O_3 impacts to public welfare due to the heavy management common for achieving optimum yields and market factors that influence associated services and additionally takes note of the PA conclusions that placing emphasis on the protection afforded to trees inherently also recognizes a level of protection afforded for crops.

Based on her consideration of the conclusions in the PA, and with particular weight given to PA findings pertaining to tree growth-related effects, as well as with consideration of CASAC's conclusion that the current standard is not adequate, the Administrator proposes to conclude that the current standard is not requisite to protect public welfare from known or anticipated effects and that revision is needed to provide increased public welfare protection, especially for sensitive vegetation and ecosystems in federally protected Class I areas and in other areas providing similar public welfare benefits. The Administrator further concludes that the scientific evidence and quantitative analyses on tree growth-related effects provide strong support for consideration of alternative standards that would provide increased public welfare protection beyond that afforded by the current O_3 secondary standard. She further notes that a revised standard would provide increased protection for other growth-related effects, including for carbon storage and for areas for which it is more difficult to determine public welfare significance, as recognized in section IV.B.2 above, as well other welfare effects of O_3, including visible foliar injury and crop yield loss.

In giving particular focus to tree growth-related effects of O_3 on public welfare, the Administrator additionally recognizes that there are alternative approaches to viewing the evidence and information, including alternative approaches to viewing, evaluating, and weighing important uncertainties. In some cases, these alternative approaches have been expressed by public commenters, leading some public commenters to recommend retaining the current standard. Given these alternative views, in addition to proposing to revise the current secondary standard, the Administrator also solicits comment on the option of retaining the standard without revision.

E. Consideration of Alternative Secondary Standards

Given her proposed conclusion that the current secondary standard is inadequate, the Administrator has then considered what revisions to the standard may be appropriate, focusing on revisions to the key standard elements of indicator, form, averaging time, and level. On the basis of the strength and coherence of the vegetation effects evidence indicating a cumulative, seasonal, concentration-weighted metric as the most appropriate approach for judging potential impacts of and protection from O_3 in ambient air, the Administrator judges that it is appropriate to consider revisions to the secondary standard that reflect this understanding and to use such a metric in identifying an appropriate level of protection and considering the protection afforded by potential alternative standards. The Administrator also judges that the current averaging time and form may also provide protection to vegetation when set at an appropriate level. Therefore, the Administrator considered whether revision to the level of the current secondary standard might provide sufficient protection to also achieve the level of air quality that is determined requisite to protect the public welfare.

The sections below address the indicator for the secondary standard (section IV.E.1), consideration of a cumulative, seasonal exposure-based

[217] As noted in section IV.A above, Congress has established areas such as national parks and wilderness areas with specific purposes including the preservation of the areas for future generations, and has identified many of those areas as Class I areas.

standard in the PA (section IV.E.2), CASAC advice and public input (section IV.E.3), analyses of air quality in the PA and subsequent to the PA (section IV.E.4) and the Administrator's proposed conclusions regarding an alternative secondary standard (section IV.E.5)

1. Indicator

In the last review of the air quality for O_3 and other photochemical oxidants and of the O_3 standard, as in other prior reviews, the EPA focused on a standard for O_3 as the most appropriate surrogate for ambient photochemical oxidants. Ozone is a long-established surrogate for ambient photochemical oxidants, among which it is by far the most widely studied with regard to effects on welfare and specifically on vegetation. The information available in this review adds to the understanding of the atmospheric chemistry for photochemical oxidants and O_3 in particular (as described in the ISA, sections 3.2 and 3.6, and summarized in section 2.2 in the PA). The 1996 Staff Paper noted that the database on vegetation effects is generally considered to raise concern at levels found in the ambient air for O_3 and, therefore, control of ambient O_3 levels has previously been concluded to provide the best means of controlling other photochemical oxidants of potential welfare concern (U.S. EPA, 1996b, p. 277). In the current review, while the complex atmospheric chemistry in which O_3 plays a key role has been highlighted, no alternatives to O_3 have been advanced as being a more appropriate surrogate for ambient photochemical oxidants. Ozone continues to be the only photochemical oxidant (other than nitrogen dioxide) that is routinely monitored and for which a comprehensive database exists (U.S. EPA, 2013a, section 3.6).

Thus, the Administrator concludes that ozone is the appropriate indicator and proposes to continue to use O_3 as indicator for a secondary standard that is intended to address effects associated with exposure to O_3, alone and in combination with related photochemical oxidants. In so doing, the Administrator recognizes that measures leading to reductions in ecosystem exposures to O_3 will also reduce exposures to other photochemical oxidants.

2. Consideration of a Cumulative, Seasonal Exposure-based Standard in the Policy Assessment

In recognition of the extensive evidence supporting a cumulative, seasonal exposure index as a biologically relevant metric for assessing potential for O_3 effects on vegetation, discussed in sections IV.B.1 above, as well as advice from CASAC in the current and last O_3 NAAQS reviews, summarized in sections IV.D.3 above and IV.E.3 below, the PA focused its consideration of alternative standards on a revised secondary standard based on a cumulative, seasonal, concentration-weighted form. The PA considered the currently available information that has been critically analyzed and characterized in the ISA, the risk and exposure information presented in the WREA, and CASAC advice and public comment with regard to support for consideration of options for alternative standards that might be expected to provide increased protection from ambient O_3 exposures over the current standard.

a. Form and Averaging Time

In considering potential forms for a revised secondary standard, the PA considers the characterization of the evidence in the ISA, summarized in section IV.B.1 above, including the ISA conclusion that exposure indices that cumulate and differentially weight the higher hourly average concentrations over a season and also include the mid-level values, such as the W126 index, offer the most scientifically defensible approach for characterizing vegetation response to ambient O_3 and comparing study findings, as well as for defining indices for vegetation protection (U.S. EPA, 2013a, section 2.6.6.1). The PA additionally considers CASAC advice in the current review, as well as that from the last review, all of which provided support for such a form. Thus, in considering alternative forms of a revised standard, the PA concludes that it is reasonable and appropriate to consider a cumulative, concentration-weighted form to provide protection against cumulative, seasonal exposures to O_3 that are known or anticipated to harm sensitive vegetation or ecosystems. The PA recognizes that such a metric is specifically designed to focus on the kind of O_3 exposures that have been shown to cause harm to vegetation and states that it would have a distinct advantage over the form of the current standard in characterizing air quality conditions potentially of concern for vegetation and in more directly demonstrating that the desired degree of protection against those conditions was being achieved (U.S. EPA, 2014c, sections 6.2 and 6.6).

With regard to the appropriate index for a cumulative seasonal form, the PA considers the evidence and background for a number of different cumulative concentration weighted indices that have been developed and evaluated in the scientific literature and in past NAAQS reviews in terms of their ability to predict vegetation response and their usefulness in the NAAQS context (U.S. EPA, 2006a, pp. 9–11 to 9–15 and pp. AX9–159 to AX9–187; U.S. EPA, 2007, pp. 7–15 to 7–16). While these various forms have different strengths and limitations, the PA notes the ISA conclusion that the W126 index, described in section IV.B.1 above, has some important advantages over other non-sigmoidally weighted cumulative indices, including its lack of a cut-off in its weighting scheme which allows for cumulation of lower O_3 concentrations (U.S. EPA, 2013a, section 9.5; U.S. EPA, 2014c, sections 6.2 and 6.6). Additionally, the W126 metric adds increasing weight to hourly concentrations from about 40 ppb to about 100 ppb, which is an important feature because ''as hourly concentrations become higher, they become increasingly likely to overwhelm plant defenses and are known to be more detrimental to vegetation'' (U.S. EPA, 2013a, p. 9–104). The PA additionally takes note of CASAC advice in the current and last review that concurred with a focus on the W126 form (Frey, 2014c, p. iii; Henderson, 2006; Samet, 2010). Based on the considerations summarized here, the PA concludes that the W126 index is the most appropriate cumulative seasonal form to consider in the context of the secondary O_3 NAAQS review.

The PA next considers the exposure periods—diurnal and seasonal—over which the W126 index would be summed in any given year. The currently available information continues to provide support for a definition of the diurnal period of interest as the 12-hour period from 8:00 a.m. to 8:00 p.m., which the EPA identified in past reviews as appropriately capturing the diurnal window with most relevance to the photosynthetic process (U.S. EPA, 2013a, section 9.5.3; 72 FR 37900, July 11, 2007). The CASAC has generally supported this 12-hour daylight period as well (Frey, 2014c; Henderson, 2006, 2007). Based on these considerations, the PA concludes that the 12-hour daylight window (8:00 a.m. to 8:00 p.m.) represents the portion of the diurnal exposure period that is most relevant to predicting or inducing plant effects related to photosynthesis and growth and thus is an appropriate diurnal period to use in conjunction with a W126 cumulative metric (U.S. EPA, 2014c, sections 6.2 and 6.6). With regard

to a seasonal period of interest, the current evidence base continues to provide support for a seasonal period with a minimum duration of three months, as described more fully in the ISA and considered in the PA (U.S. EPA, 2013a, section 9.5.3; U.S. EPA, 2014c, sections 6.2 and 6.6). The CASAC has also indicated support for such a three month period (Frey, 2014c; Samet, 2010; Henderson, 2006). The PA thus concludes that it is appropriate to identify the seasonal W126 index value as that derived from the consecutive 3-month period within the O_3 season with the highest W126 index value.

The PA additionally considers the period of time over which a cumulative seasonal W126-based standard should be evaluated, considering the support for both a single year form and a form averaged over three years (U.S. EPA, 2014c, pp. 6–29 through 6–33). The PA considers the evidence of effects associated with single year and multiple year exposures as well as their potential public welfare significance. The PA also considers comments from CASAC, including their comment in the current review that ''[t]he CASAC does not recommend the use of a three-year averaging period'' and that they ''favor a single-year period for determining the highest three-month summation which will provide more protection for annual crops and for the anticipated cumulative effects on perennial species'' (Frey, 2014c, p. iii).

The PA considered O_3-induced effects that can occur with a single year's exposure, including visible foliar injury, growth reduction in annual and perennial species and yield loss in annual crops (U.S. EPA, 2014c, section 6.3). While recognizing that there are a number of O_3-induced effects that have the potential for public welfare significance within the annual timeframe, the PA also notes the uncertainties associated with these effects that complicate consideration of the level of appropriate protection on an annual basis for such effects in order to protect the public welfare from known or anticipated adverse effects, and thus recognizes the possibility that a multiple-year form could be considered to provide a more consistent target level of protection for certain effects (U.S. EPA, 2014c, pp. 6–29 to 6–31). With regard to visible foliar injury, the ISA notes that ''the degree and extent of visible foliar injury development varies from year to year and site to site . . . even among co-members of a population exposed to similar O_3 levels, due to the influence of co-occurring environmental and genetic factors'' (U.S. EPA, 2013a, p. 9–38; U.S. EPA, 2014c, p. 6–30). Additionally, the PA takes note of the difficulty and complexity shown by the WREA analyses with regard to identifying W126 index values that would provide consistent protection on an annual basis given likely fluctuations in annual O_3 and soil moisture conditions (U.S. EPA, 2014c, p. 6–30).

The PA additionally notes evidence of some O_3 effects on perennial species that may result from a single season's elevated O_3 exposures, such as reduced bud size or starch content, which may have the potential for some ''carry over'' of effects on plant growth or reproduction in the subsequent season. Another effect where such potential for ''carry over'' has been noted with elevated O_3 exposure is reduction in below-ground carbohydrate reserves which can impair growth in subsequent seasons (U.S. EPA, 2014c, pp. 6–30 to 6–31; U.S. EPA, 2013a, pp. 9–43 to 9–44 and p. 9–86). The PA notes that the occurrence of such annual effects of elevated O_3 exposures over multiple years may contribute to a potential to be compounded, increasing the potential for effects at larger scales (*e.g.,* population, ecosystem). In the PA, staff notes that multiple consecutive years of critical O_3 exposures might be expected to result in larger impacts on forested areas than intermittent occurrences of such exposures due to the potential for compounding or carry-over effects on tree growth (U.S. EPA, 2014c, pp. 6–29 to 6–31).

In light of the above summarized considerations for potential compounding of carry-over effects, the PA concludes that the public welfare significance of the effects that can occur as a result of three-year O_3 exposures are potentially greater than those associated with a single year of such exposure. Thus, to the extent that the focus for public welfare protection to be afforded by the secondary O_3 standard is on long-term effects that occur in sensitive tree species in natural forested ecosystems, including federally protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, the PA concludes that a standard with a form that evaluates the cumulative seasonal index across multiple years might be considered to provide a more appropriate match to the nature of O_3-related effects on vegetation upon which the secondary O_3 standard is focused. In considering such forms, the PA focuses on one that averages the W126 index values across three years (U.S. EPA, 2014c, section 6.2).

With regard to single-year and three-year forms, the PA considers a WREA analysis that examined the extent to which cumulative RBL across a three-year period might be underestimated when each year's RBL is derived from the three-year average W126 index value versus each single-year W126 index value for each of three years (in which no other influence on plant growth is presumed to change). This analysis indicates that use of the three-year average may lead to an underestimation, although of relatively small magnitude (U.S. EPA, 2014b, section 6.2.1.4). The PA notes that this limited analysis does not account for moisture levels and other environmental factors that could affect plant growth and that vary from year to year. When considering an appropriate level for a form that averages W126 index values across three years, the PA also recognizes the importance of considering the extent to which the cumulative effect of different average W126 exposures across the three-year period would be judged adverse (U.S. EPA, 2014c, p. 6–31).

Although single-year W126 index values were not separately analyzed in the PA analysis of recent monitoring data, the data indicate appreciable variation in cumulative, seasonal O_3 concentrations among monitor locations meeting different levels of a standard of the current form (U.S. EPA 2014c, section 6. Appendix 2B).Therefore, a standard with an annual form would have the cumulative seasonal index values be at or lower than the level of the standard in all years and, noting the inter-annual observed variability in seasonal W126 index values, could be appreciably below the standard level in some years. For a standard with a form that averages the cumulative seasonal index values across three consecutive years, the annual seasonal index value could be above the level in some years, but would have to be below it in others within the same three-year period, thus restricting the air quality for a given area to have no more than two years out of three with a W126 index value above the standard level, and depending on magnitude of each year's index, potentially having no more than one.

In its consideration of one year as compared to three year forms, the PA also considers implications with regard to stability of air quality programs that implement the NAAQS (U.S. EPA, 2014c, pp. 6–31 to 6–32). The PA notes that a standard based on a single year W126 index would be expected to have a less stability relative to a standard based on a form that averages seasonal indices across three consecutive years, given the potential for large year-to-year variability in annual W126 index values in areas across the country. Thus, a

three-year evaluation period can contribute to greater public welfare protection by limiting year-to-year disruptions in ongoing control programs that would occur if an area was frequently shifting in and out of attainment due to extreme year-to-year variations in meteorological conditions. This greater stability in air quality management programs would thus facilitate achievement of the protection intended by a standard. Such considerations of stability often receive particular weight in NAAQS reviews, such as those resulting in selection of the form for the current O_3 primary and secondary standards (62 FR 38856, July 18, 1997), as well as the primary standards for nitrogen dioxide (75 FR 6474, February 9, 2010) and sulfur dioxide (75 FR 35520, June 22, 2010). See also *ATA III,* 283 F. 3d at 374–75 (recognizing programmatic stability as a legitimate consideration in the NAAQS standard-setting process).

Thus, to the extent that emphasis continues to be placed on protecting against effects associated with multi-year exposures and maintaining more year-to-year stability of public welfare protection, the PA concludes that it is appropriate to consider a secondary standard form that is an average of the seasonal W126 index values across three consecutive years. The PA concludes that such a form might be appropriate for a standard intended to achieve the desired level of protection from longer-term effects, including those associated with potential compounding, and that such a form might be concluded to contribute to greater stability in air quality management programs, and thus, greater effectiveness in achieving the desired level of public welfare protection, than that might result from a single year form (U.S. EPA, 2014c, section 6.6).

The PA additionally recognized that to the extent the Administrator finds it useful to consider the public welfare protection that might be afforded by a revised primary standard, this is appropriately judged by evaluating the impact of attainment of such a revised primary standard on O_3 exposures in terms of the cumulative seasonal W126-based exposure index.

b. Level

In considering an appropriate range of levels to consider for a W126-based standard, the PA notes that, due to the variability in the importance of the associated ecosystem services provided by different species at different exposures and in different locations, as well as differences in associated uncertainties and limitations, both the species present and their public welfare significance, in addition to the magnitude of the ambient concentrations, are essential considerations in drawing conclusions regarding the significance or magnitude of public welfare impact. Therefore, in development of the PA conclusions, staff took note of the complexity of judgments to be made by the Administrator regarding the adversity of known and anticipated effects to the public welfare and recognized that the Administrator's ultimate judgments on the secondary standard will most appropriately reflect an interpretation of the available scientific evidence and exposure/risk information that neither overstates nor understates the strengths and limitations of that evidence and information.

As described in section IV.D.1 above, the PA employed a paradigm, which has evolved over the course of the O_3 and other secondary NAAQS reviews, to assist in putting the available science and exposure/risk information into the public welfare context (U.S. EPA, 2014c, section 5.1). This paradigm recognizes that the significance to the public welfare of O_3-induced effects on sensitive vegetation growing within the U.S. can vary depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Accordingly, any given O_3-related effect on vegetation and ecosystems (*e.g.,* biomass loss, crop yield loss, visible foliar injury) may be judged to have a different degree of impact on or significance to the public welfare depending, for example, on whether that effect occurs in a Class I area, a city park, or commercial cropland. This approach also includes consideration of impacts to ecosystem goods and services, which are an important category of public welfare effects with an obvious relationship to consideration of intended use (73 FR 16492, March 27, 2008).

In considering potential levels for an alternative standard based on the W126 metric, the PA focused primarily on impacts on tree growth, crop yield loss, and visible foliar injury, as well as impacts on the associated ecosystem services, while taking note of the uncertainties and limitations associated with several key aspects of this information. In addition to uncertainties related to the WREA air quality scenarios and assessments summarized in section IV.C above, the PA also recognized uncertainties associated with the evidence underlying the tree seedling and crop E–R functions (U.S. EPA, 2014c, section 6.3). These include uncertainties regarding intra-species variability due to the different numbers of studies that exist for different species so that the weight of evidence is not the same for each species. Those species with more than one study show variability in response and E–R functions. The potential variability in less well-studied species is, however, unknown (U.S. EPA, 2013a, pp. 9–123 to 9–125; U.S. EPA, 2014b, section 6.2.1.2, and Table 6–27). The PA also recognizes uncertainty regarding the extent to which tree seedling E–R functions can be used to represent mature trees since seedling sensitivity has been shown in some cases to not reflect mature tree O_3 sensitivity in the same species and uncertainty in the relationship of O_3 effects on tree seedlings (*e.g.,* relative biomass loss) in one or a few growing seasons to effects that might be expected to accrue over the life of the trees extending into adulthood (U.S. EPA, 2013a, section 9.6 and pp. 9–52 to 9–53; U.S. EPA, 2014b, sections 6.2.1.1, 6.2.1.4 and Tables 6–5 and 6–27).

With respect to tree growth, the PA gave primary consideration to relative biomass loss estimates derived from the E–R functions, described in section IV.B.1.b above and in the PA, while also considering WREA risk/exposure estimates related to this effect (U.S. EPA, 2014c, section 6.4). The PA takes note of the different index value estimates presented in Table 6–1 of PA (Table 8 below) with regard to the number of studied species below different response benchmarks, as well as with regard to the median response. The PA additionally considers the WREA estimates regarding: (1) percent of assessed geographic area exceeding 2% weighted relative biomass (U.S. EPA, 2014c, Table 6–2); (2) number of assessed Class I areas with tree seedling weighted relative biomass loss estimates below 2% (U.S. EPA, 2014c, Table 6–3); and (3) the percent median biomass loss across counties for different air quality scenarios (U.S. EPA, 2014c, Table 5–5). The PA further notes other WREA estimates for effects on ecosystem services related to public welfare, such as carbon sequestration and air pollutant removal. With respect to crop yield loss, the PA notes the summary of RYL estimates for individual crop species and for the median across species (Table 8), and the WREA risk/exposure estimates (U.S. EPA, 2014b, Section 6.3). The PA also notes information available on visible foliar damage to species occurring in areas preserved for their natural character,

such as federal Class I areas, and the analyses in the WREA evaluating biosite data and several benchmarks of injury (U.S. EPA, 2014b, section 5.4.2).

TABLE 8—TREE SEEDLING BIOMASS LOSS AND CROP YIELD LOSS ESTIMATED FOR O_3 EXPOSURE OVER A SEASON

W126 value for exposure period	Tree seedling RBL [a]		Crop RYL [c]	
	Median value	Individual species	Median value	Individual species
21 ppm-hrs	Median species w. 6.8% loss [b].	≤ 2% loss: 3/11 species ..... ≤5% loss: 5/11 species ..... ≤10% loss: 7/11 species ..... ≤15% loss: 10/11 species ..... >40% loss: 1/11 species	Median species w. 7.7% loss [d].	≤5% loss: 4/10 species. >5, <10% loss: 3/10 species. >10, <20% loss: 3/10 species.
19 ppm-hrs	Median species w. 6.0% loss [b].	≤2% loss: 3/11 species ..... <5% loss: 5/11 species ..... ≤10% loss: 7/11 species ..... ≤15% loss: 10/11 species ..... >30% loss: 1/11 species	Median species w. 6.4% loss [d].	≤5% loss: 5/10 species. >5, <10% loss: 3/10 species. >10, <20% loss: 2/10 species.
17 ppm-hrs	Median species w. 5.3% loss [b].	≤2% loss: 5/11 species ..... <5% loss: 5/11 species ..... ≤10% loss: 9/11 species ..... 15% loss: 10/11 species ..... >30% loss: 1/11 species	Median species w. 5.1% loss [d].	≤5% loss: 5/10 species. >5, <10% loss: 3/10 species. >10, <20% loss: 2/10 species.
15 ppm-hrs	Median species w. 4.5% loss [b].	≤2% loss: 5/11 species ..... ≤5% loss: 6/11 species ..... ≤10% loss: 10/11 species ..... >30% loss: 1/11 species	Median species w. ≤5% loss [d].	≤5% loss: 6/10 species. >5, <10% loss: 4/10 species.
13 ppm-hrs	Median species w. 3.8% loss [b].	≤2% loss: 5/11 species ..... <5% loss: 7/11 species ..... <10% loss: 10/11 species ..... >20% loss: 1/11 species	Median species w. ≤5% loss [d].	≤5% loss: 6/10 species. >5, <10% loss: 4/10 species.
11 ppm-hrs	Median species w. 3.1% loss [b].	≤2% loss: 5/11 species ..... ≤5% loss: 8/11 species ..... ≤10% loss: 10/11 species ..... >20% loss: 1/11 species	Median species w. ≤5% loss [d].	≤5% loss: 9/10 species. >5, <10% loss: 1/10 species.
9 ppm-hrs	Median species w. 2.4% loss [b].	≤2% loss: 5/11 species ..... ≤5% loss: 10/11 species ..... >20% loss: 1/11 species	Median species w. ≤5% loss [d].	≤5% loss: all species.
7 ppm-hrs	Median species w. ≤2% loss [b].	≤2% loss: 7/11 species ..... ≤5% loss: 10/11 species ..... >15% loss: 1/11 species	Median species w. ≤5% loss [d].	≤5% loss: all species.

[a] Estimates are based on the 11 E–R functions for tree seedlings described in WREA, Appendix 6F and discussed in the PA, section 5.2.1, with the exclusion of cottonwood in consideration of CASAC comments on differences of that study from the other controlled E–R studies (Frey, 2014b, 2014c).

[b] This is the median of the composite E–R functions for 11 tree species from the WREA, Appendix 6F (discussed in the PA, section 5.2.1).

[c] Estimates here are based on the 10 E–R functions for crops (from the PA, Appendix 6F and section 5.3.1).

[d] This median value is the median of the composite E–R functions for 10 crops from WREA, Appendix 6F (also discussed in the PA, section 5.3.1).

Given the wide variation in sensitivity of studied tree species to O_3-induced relative biomass loss, the PA focused consideration on both median species values and individual species responses and RBL estimates for a given range of W126 index values. In this consideration, the PA took note of CASAC's advice regarding RBL levels, specifically their emphasis on a benchmark of median relative tree biomass loss at or below 2% and their view that a 6% median relative biomass loss is ''unacceptably high.'' The median tree species RBL estimate is at or below 2% only at the lowest W126 level assessed, 7 ppm-hrs. At incrementally higher W126 index levels, the median RBL is also incrementally higher, so that at W126 index values of 9, 11, 13, 15, 17 and 19 ppm-hrs, the median RBL increases to 2.4%, 3.1%, 3.8%, 4.5%, 5.3% and 6.0%, respectively. Thus, the median species biomass loss is below 6%, the level characterized by the CASAC as unacceptably high, across the W126 range of 7 to 17 ppm-hrs, for which it varies from approximately 2% to approximately 5%. Given this finding, the PA discussion of a range of levels appropriate to consider focuses on this range. In focusing on this range, the PA considers the full array of CASAC advice with regard to interpretation of the evidence and exposure/risk information on vegetation-related effects of O_3, as well as the role of the Administrator's judgments in identifying the level of air quality that is requisite to protect public welfare from adverse effects, as noted in section IV.A above.[218]

The PA recognizes that public welfare judgments may reasonably be informed by a range of biomass loss benchmarks, in contexts of considering both median RBL estimates and RBL estimates for individual species. Accordingly, in considering individual tree species estimates, the PA notes the value of additionally characterizing the RBL

[218] In the context of the O_3 standard, such judgments include: The weight to give the evidence of specific vegetation-related effects estimated to result across a range of cumulative seasonal concentration-weighted O_3 exposures; the weight to give associated uncertainties, including those related to the variability in occurrence of such effects in specific areas of U.S., such as those of particular public welfare significance; and, judgments on the extent to which such effects in such areas may be considered adverse to public welfare.

estimates in comparison to higher loss levels such as 10% or 15%.

For every W126 value over the full range from 7 to 17 ppm-hrs, the RBLs for each of five species is less than 2% (Table 8), which is the lower benchmark that CASAC identified for tree species. Accordingly, the PA focused attention on the remaining six more sensitive studied species (*i.e.,* eastern white pine, aspen, tulip poplar, ponderosa pine, red alder, and black cherry) to evaluate the protection against tree seedling biomass loss at different W126 levels within the range from 17 to 7 ppm-hrs. At a W126 index value of 17 ppm-hrs, one of these six species (red alder) has a RBL estimate below 6%, while at the W126 index value of 7 ppm-hrs, five of these six species have RBLs below 6% (eastern white pine, aspen, tulip poplar, ponderosa pine, red alder). Taken together with the more tolerant species, the proportion of the studied tree species with RBLs below 6% are 6 of 11, 7 of 11, 8 of 11, and 10 of 11 at W126 index values of 17, 15, 13, and 11 ppm-hrs, respectively.

With regard to other, higher, RBL benchmark levels and estimates for all 11 species, the PA notes that 9 of 11 studied tree species have a predicted RBL below 10% at the W126 level of 17 ppm-hrs, while 10 of 11 species have a predicted RBL below 10% for W126 levels of 15 to 7 ppm-hrs. In addition, 10 of 11 studied tree species have a predicted RBL below 15% for W126 levels of 17 to 7 ppm-hrs. The PA notes that the RBL estimates for black cherry, the most sensitive of the 11 species, remain above 15% for W126 index values across the range from 17 to 7 ppm-hrs, making unclear the extent to which black cherry estimates might inform consideration of different W126 exposures within this range (U.S. EPA, 2014c, section 6.6 and Table 6–1; U.S. EPA, 2014b, section 6.2 and Appendix 6A).

While recognizing the limitations and uncertainties associated with the WREA air quality scenarios with regard to their representation of conditions just meeting different three-year average W126 index values (as summarized in section IV.C.1 above), including the potential underestimation of the highest O_3 concentrations, the PA additionally considers several WREA RBL analyses (U.S. EPA, 2014c, section 6.3). In the WREA characterization of the number of counties where the median RBLs were greater than 2%, 7% of the counties have median RBLs greater than 2% in the 15 and 11 ppm-hrs W126 scenarios, as compared to 8% for the current standard (U.S. EPA, 2014c, Table 5–5; U.S. EPA, 2014b, Table 6–7). The percentage is 6% in the 7 ppm-hrs W126 scenario. Of the 221 counties (7% of counties) estimated to have a median RBL above 2% for the 15 ppm-hrs scenario, 203 of those counties have a RBL greater than 2% because of the presence of black cherry (U.S. EPA, 2014c, section 6.3).

In considering the potential magnitude of the ecosystem impact of O_3-related biomass effects on tree growth, the PA additionally focused on the WREA estimates of weighted RBL for the W126 air quality scenarios (U.S. EPA, 2014b, section 6.8). For the current standard and the three W126 scenarios, the percent of total assessed area having weighted RBL greater than 2% was 0.2%, 0.2%, 0.1% and <0.1%, respectively (U.S. EPA, 2014c, Table 6–2; U.S. EPA 2014b, Table 6–25). In giving particular attention to estimates for Class I areas, the PA notes that for all four scenarios, the WREA estimates indicate weighted RBL greater than 2% in one or two of the 145 assessed nationally protected Class I areas (U.S. EPA, 2014c, sections 6.3 and 6.6).

In considering potential impacts on ecosystem services related to reductions in O_3 effects on tree growth, the PA particularly recognizes that impacts on climate regulation can reasonably be concluded to be potentially significant from a public welfare perspective. In additionally recognizing that carbon sequestration has been identified as a potentially important tool for managing anthropogenic impacts on climate, the PA considers the WREA estimates of potential increases in forestry carbon storage for ambient O_3 reductions in the three W126 air quality scenarios (U.S. EPA, 2014c, sections 6.3 and 6.6; U.S. EPA, 2014b, section 6.6.1). The WREA estimates additional forestry carbon storage potential of 13, 593 and 1,600 $MMtCO_2e$ (over 30 years) for the W126 scenarios of 15, 11 and 7 ppm-hrs, respectively, as compared to the current standard (U.S. EPA, 2014b, Table 6–18). Compared to the absolute estimate for the current standard scenario (approximately 89,000 $MMtCO_2e$, over 30 years), these amounts represent additional storage of less than 0.1%, just under 1% and under 2% for the 15, 11 and 7 ppm-hrs scenarios, respectively (U.S. EPA, 2014b, section 6.6.1 and Appendix 6B).

The PA additionally considers the WREA estimates for five urban areas of how reduced growth of O_3-sensitive trees in urban forests may affect air pollutant removal (U.S. EPA, 2014b, sections 6.6.2 and 6.7 and Appendix 6D). As with the national estimates, estimates for all five case study areas indicate generally small differences between the current standard and the three W126 scenarios (U.S. EPA, 2014c, Table 6–5). The PA additionally notes significant uncertainties and limitations associated with WREA estimates related to carbon sequestration and air pollution removal (U.S. EPA, 2014b, Table 6–27; U.S. EPA, 2014c, sections 6.3 and 6.6), some of which are summarized in section IV.C.2.b above. The PA recognizes that, as with consideration of other pertinent evidence and exposure/risk information, the Administrator's consideration of WREA estimates for these ecosystem services will involve judgments regarding the appropriate weight to place on such uncertainties as well as the potential impacts to the public welfare of the estimates.

The PA additionally considers the biomass effects of O_3 on crops estimated for different W126 index values across the range identified above. For this consideration, the PA focuses on the 10 crops for which robust E–R functions have been established, as described in section IV.B.1 above: Barley, lettuce, field corn, grain sorghum, peanut, winter wheat, field cotton, soybean, potato and kidney bean (U.S. EPA, 2013a; U.S. EPA, 2014b, section 6.5 and Figure 6–3). In evaluating this information, the PA takes note of CASAC's comment regarding significance of 5% for median crop relative yield loss (RYL). The PA finds that the median crop RYL is at or below 5% for all W126 index values from 7 to 17 ppm-hrs and observes that this finding makes it unclear to what extent this information informs consideration of levels within this range. The RBL estimates for half of the ten individual species are below 5% RYL at 17 ppm-hrs. The number of the ten individual crops with RYL below 5% is six for W126 values of 15 and 13 ppm-hrs, nine for a W126 value of 11 ppm-hrs and ten for W126 levels of 9 and 7 ppm-hrs. Recognizing that different crops are likely to have different values or importance to public welfare, the PA also considers the RYL estimates across the W126 range for individual species.

In considering these RYL estimates, the PA recognizes that they do not reflect the influence of the heavy management of agricultural crops that is common in the U.S. and so cannot be easily interpreted with regard to potential public welfare significance. In light of the median RYL estimates of approximately 5% or lower for W126 index values at and below 17 ppm-hrs, the PA gives less emphasis to consideration of crop RYL, while noting that this information indicates that a secondary standard revised to provide

additional protection for vegetation with attention to tree growth, would be expected to also provide additional protection to crops over that provided by the current standard (U.S. EPA, 2014c, section 6.6).

The PA also considers the evidence and exposure/risk information with regard to visible foliar injury and the extent to which that might inform consideration of potential alternative secondary standards appropriate for the Administrator to consider. Specifically, the PA notes the findings of the WREA analyses of the nationwide USFS/FHM biosite dataset (2006–2010) that while soil moisture conditions influence the proportion of biosites with O_3-related visible foliar injury, as described in section IV.B.1.a above, the proportion of such sites increases appreciably with increasing W126 index values up to approximately 10 ppm-hrs, while relatively little or no change in incidence of injury is seen with O_3 exposures at higher W126 index values (U.S. EPA 2014b, Chapter 7, Figure 7–10). The PA additionally notes that visible foliar injury has been identified by the federal land managers as a diagnostic tool for informing conclusions regarding potential O_3 impacts on potentially sensitive AQRVs (USFS, NPS, FWS, 2010), which the PA concludes indicates that such O_3-induced impacts might be considered to have the potential to impact the public welfare in scenic and/or recreational areas during years they occur.

The PA was unable, however, to identify any guidance for federal land managers regarding at what spatial scale or what degree of severity visible foliar injury might be sufficient to trigger protective action based on this potential impact on AQRVs. The PA states that there does not appear to be consensus in the literature regarding severity of visible foliar injury and risks to plant functions or services, additionally noting that CASAC, while identifying percent biomass loss and yield loss benchmarks for tree seedlings and commodity crops, respectively, did not provide any benchmark or criteria for consideration of O_3 impacts related to this endpoint. Further, as in previous reviews, the ISA concludes visible foliar injury is not always a reliable indicator of other negative effects on vegetation, making it difficult to relate visible foliar injury symptoms to other vegetation effects such as individual plant growth, stand growth, or ecosystem characteristics (U.S. EPA, 2013a, section 9.4.2, p. 9–39). Additionally, although evidence shows visible foliar injury can occur under very low cumulative O_3 exposures, ''. . . the degree and extent of visible foliar injury development varies from year to year and site to site . . ., even among co-members of a population exposed to similar O_3 levels, due to the influence of co-occurring environmental and genetic factors'' (U.S. EPA 2013a, section 9.4.2, p. 9–38). Thus, while the PA recognizes visible foliar injury as an important O_3 effect which, depending on severity and spatial extent may reasonably be concluded to be of public welfare significance, most particularly in nationally protected areas such as Class I areas, it additionally recognizes the appreciable variability in this endpoint, which poses challenges to giving it primary emphasis in identifying potential alternative standard levels.

On the basis of all the considerations described above, including the evidence and exposure/risk analyses, and advice from CASAC, the PA concludes that a range of W126 index values appropriate for the Administrator to consider in identifying a secondary standard that might be expected to provide the requisite protection to the public welfare from any known or anticipated adverse effects, extends from 7 to 17 ppm-hrs. The PA notes, however, the role of judgments by the Administrator in such decisions, as recognized above. In selecting this range, the PA primarily considers the evidence- and exposure/risk-based information for cumulative seasonal O_3 exposures represented by W126 index values (including those represented by the WREA average W126 scenarios) associated with biomass loss in studied tree species, both in and outside areas that have been afforded special protections. The PA recognizes that tree biomass loss can be an indicator of more significant ecosystem-wide effects which might reasonably be concluded to be significant to public welfare. For example, when biomass loss occurs over multiple years at a sufficient magnitude, it is linked to some level of effects on an array of ecosystem-level processes, such as nutrient and water cycles, changes in above and below ground communities, carbon storage and air pollution removal, that benefit the public welfare (U.S. EPA, 2014c, Figure 5–1). In focusing on tree biomass effects, the PA gave emphasis to CASAC's judgment that a 6% median RBL is unacceptably high, and that the 2% median RBL is an important benchmark to consider. The PA notes that for the lower W126 value of 7 ppm-hrs that the median tree species biomass loss is at or below 2% and that for the upper value of 17 ppm-hrs that the median tree biomass loss is below 6%.[219]

In considering the stability and potential for associated greater public welfare protection offered by a three-year form, as well as based on the recognition that in any given year in the environment, other environmental factors can influence the extent to which O_3 may have the impact predicted by the E–R functions on which much of the range discussion above focuses, the PA gave careful consideration to the support for consideration of potential alternative W126 based standards with levels in the range identified above (17 ppm-hrs to 7 ppm-hrs) with a three-year average form.

Thus, the PA concludes that in staff's view, the evidence- and exposure/risk-based information relevant to tree biomass loss and the associated ecosystem services important to the public welfare support consideration of a W126-based secondary standard with index values within the range of 7 to 17 ppm-hrs, and a form averaged over three years. In reaching this conclusion, the PA gave particular consideration to the importance of considering the lasting or carry-over effects that can derive from single year exposures of perennial plants, recognizing the importance of considering the available evidence and exposure/risk based information related to such effects, as well as associated uncertainties. The PA additionally recognized that there is limited information to discern differences in the level of protection afforded for cumulative growth-related effects by potential alternative W126-based standards of a single year form as compared to a three-year average form. Lastly, the PA recognizes the role of policy judgments required of the Administrator with regard to the public welfare significance of identified effects, the appropriate weight to assign the range of uncertainties inherent in the evidence and analyses, and, ultimately, in identifying the requisite protection for the secondary O_3 standard. Examples of areas where the Administrator's judgments would be expected include those stemming from consideration of the effects associated with longer-term conditions and the role that year-to-year exposure variability may play in associated public welfare impacts, as well as the objectives for consideration of tree species biomass loss estimates in relationship to identified benchmarks (*e.g.,* 2% or greater).

[219] We note that a W126 index value of 19 ppm-hrs is estimated to result in a median RBL value of 6%, as shown in Table 2 above.

The PA also concludes that, to the extent the Administrator finds it useful to consider the public welfare protection that might be afforded by a revised primary standard, this is appropriately judged through the use of a cumulative seasonal W126-based exposure metric, a metric considered appropriate for evaluating impacts on vegetation. For example, comparison of the air quality conditions (expressed in terms of W126 exposures) expected to result from a revised primary standard to the W126-based exposures concluded to provide requisite public welfare protection would thus inform a judgment of whether a secondary standard set identical to a revised primary standard would be expected to achieve the appropriate level of air quality. The PA notes that such a comparison would be in terms of a metric considered appropriate for evaluating impacts on vegetation which inform conclusions on public welfare impacts. The PA further concludes that the drawing of conclusions with regard to the public welfare protection afforded by such a standard should entail consideration of the air quality conditions likely to be achieved in terms of the cumulative seasonal W126-based metric described above.

Accordingly, the PA describes several analyses of air quality data that might inform such consideration (U.S. EPA, 2014c, section 6.4), and notes the importance of taking into account associated uncertainties, including those associated with the limited monitor coverage in many rural areas, such as those in the West and Southwest regions and at high elevation sites. Additional such analyses, based on more recent O_3 monitoring data, have been developed since the completion of the PA. All of these analyses are summarized in section IV.E.4 below. In reaching conclusions on appropriate policy options for a revised secondary standard the Administrator has considered the findings of these analyses, as described in section IV.E.5 below.

3. CASAC Advice

Beyond the evidence- and exposure/risk-based considerations in the PA discussed above, the EPA's consideration of a revised secondary standard also takes into account the advice and recommendations of CASAC. The EPA also considered public comments received to date, some of which urged the consideration of a secondary standard with a cumulative seasonal form using the W126 metric and a level within the range of 7 to 15 ppm-hrs or in the low end of this range,[220] while others have urged retaining the existing form and averaging time due to their view of a lack of new information to support a distinct secondary standard.

In advice offered on a revised secondary standard in the current review, similar to advice in the last review, including advice offered on the 2010 proposed reconsideration, the CASAC recommended ''retaining the current indicator (ozone) but establishing a revised form of the secondary standard to be the biologically relevant W126 index accumulated over a 12-hour period (8 a.m.–8 p.m.) over the 3-month summation period of a single year resulting in the maximum value of W126'' (Frey, 2014c, p. iii). With regard to the level, the CASAC recommended that ''that the level associated with this form be within the range of 7 ppm-hrs to 15 ppm-hrs to protect against current and anticipated welfare effects of ozone'' and that ''CASAC does not support a level higher than 15 ppm-hrs'' (Frey, 2014c, p. iii). The CASAC additionally stated that ''[i]n reaching its scientific judgment regarding the indicator, form, summation time, and range of levels for a revised secondary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public welfare,'' while also acknowledging ''that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act'' (Frey, 2014c, p. iii).

In providing advice on a range for the secondary standard, the CASAC noted a W126 index value for which the median tree species RBL estimate was 6 percent, and the median crop species RBL estimate was over 5 percent, stating that ''[t]hese levels are unacceptably high'' (Frey, 2014c, p. iii).[221] In addition, regarding consideration of relative biomass loss benchmarks for tree seedlings, the CASAC stated that ''[a] 2% biomass loss is an appropriate scientifically based value to consider as a benchmark of adverse impact for long-lived perennial species such as trees, because effects are cumulative over multiple years'' (Frey, 2014c, p. 14). In so stating, the CASAC referenced findings for biomass loss in aspen exposed to elevated O_3 over seven years, citing Wittig et al., 2009.[222] The CASAC additionally pointed to the report of the 1996 workshop sponsored by the Southern Oxidants Study group (Heck and Cowling, 1997, noted in section IV.B.2 above) which described a general consideration of 1–2% per year growth reduction in making judgments the group identified as appropriate for the endpoint of growth effects in trees, without providing an explicit rationale for the identified percentages (Frey, 2014c, p. 14). The CASAC also commented that ''it is appropriate to identify a range of levels of alternative W126-based standards that includes levels that aim for not greater than 2% RBL for the median tree species'' (Frey, 2014c, p. 14). The CASAC noted that the ''level of 7 ppm-hrs is the only level analyzed for which the relative biomass loss for the median tree species is less than or equal to 2 percent'' indicating that 7 ppm was appropriate lower bound for the recommended range (Frey, 2014c, p. 14).

With regard to consideration of effects on crops, the CASAC, as noted above, described median species RYL over 5% yield loss as ''unacceptably high.'' The CASAC further noted that ''[c]rop loss appears to be less sensitive than these other indicators, largely because of the CASAC judgment that a 5% yield loss represents an adverse impact, and in part due to more opportunities to alter management of annual crops'' (Frey, 2014c, p. 14).

The CASAC acknowledged that ''the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act'', while further providing its own policy recommendations, including the following (Frey, 2014c, p. iii).

> [T]he CASAC advises that a level of 15 ppm-hrs for the highest 3-month sum in a single year is requisite to protect crop yield loss, but that lower levels provide additional protection against crop yield loss. Furthermore, there are specific economically significant crops, such as soybeans, that may not be protected at 15 ppm-hrs but would be protected at lower levels. A level below 10 ppm-hrs is required to reduce foliar injury. A level of 7 ppm-hrs is protective of relative biomass loss for trees and offers additional

[220] Public comment received thus far in this review are in the docket EPA–HQ–OAR–2008–0699, accessible at *www.regulations.gov*

[221] The CASAC made this comment while focusing on Table 6–1 in the second draft PA and the entry for 17 ppm-hrs. That table was revised for inclusion in the final PA in consideration of CASAC comments on the E–R function for eastern cottonwood, such that the RBL estimates for 17 ppm-hrs in the final table (see Table 2 above) are below the values CASAC viewed as ''unacceptably high''.

[222] The way in which the statement pointing to the aspen seven-year biomass loss value from Wittig et al (2009) relates to CASAC's view with regard to 2%, however, is unclear as the original source for this finding (cited in Wittig et al., 2009) indicates yearly relative biomass loss values during this seven year exposure that are each well above 2%, and, in fact, are all above 20% (King, et al., 2005).

protection against crop yield loss and foliar injury. Therefore, 7 ppm-hrs is protective of ecosystem services. Thus, lower levels within the recommended range offer a greater degree of protection of more endpoints than do higher levels within the range.

Additionally, in regard to consideration of form, the CASAC noted that ''[i]f, as a policy matter, the Administrator prefers to base the secondary standard on a three-year averaging period for the purpose of program stability, then the level of the standard should be revised downward such that the level for the highest three-month summation in any given year of the three-year period would not exceed the scientifically recommended range of 7 ppm-hrs to 15 ppm-hrs'' (Frey, 2014c, pp. iii and iv). In related manner, the CASAC noted that a three-year average W126 level of 13 ppm-hrs may be appropriate depending on consideration of year-to-year variability and such policy considerations (Frey, 2014c, p. iv).

Lastly, in comments recognizing uncertainties associated with the evidence and exposure and risk analyses, the CASAC stated that ''there is sufficient scientific evidence, and sufficient confidence in the available research results, to support the advice we have given above for this review cycle of the primary and secondary standards'' (Frey, 2014c, p. iv).

4. Air Quality Analyses

As described in section II.D. above, the PA concludes with regard to the primary standard that it is appropriate for the Administrator to consider revision of the level to within the range of 60 to 70 ppb. In consideration of this conclusion for the primary standard, although the PA also concludes it is appropriate to consider a revised secondary standard with a cumulative, seasonal, concentration-weighted form, the PA recognized that, it may be practical to consider the extent to which a revised secondary standard in the form of the current secondary standard might be expected to also reduce and provide protection from cumulative seasonal exposures of concern, noting that, for example, if a clear and robust relationship was found to exist between 8-hour daily peak O_3 concentrations and cumulative, seasonal exposures, the averaging time and form of the current standard might be concluded to have the potential to be effective as a surrogate (U.S. EPA, 2014c, section 6.4).

Therefore, the PA evaluated what the available information indicated with regard to control of cumulative O_3 exposures that might be afforded by alternative secondary standards with the averaging time and form of the current standard (a three-year average of 4th highest 8-hour average concentrations). The available information addressing this point includes a ''focus study'' in the ISA, and several air quality analyses described in the PA, chapters 2, 5 and 6 and Appendix 2b.[223] Additionally, a similar air quality analysis performed with more recent monitoring data is now available and is also described here.

The focus study described in the ISA examined the diel variability in O_3 concentrations in six rural areas between 2007 and 2009 (U.S. EPA, 2013a, pp. 3–131 to 3–133). The ISA reported that ''[t]here was considerable variability in the diel patterns observed in the six rural focus areas'' with the three mountainous eastern sites exhibiting a ''generally flat profile with little hourly variability in the median concentration and the upper percentiles,'' while the three western rural areas demonstrated a ''clear diel pattern to the hourly O_3 data with a peak in concentration in the afternoon similar to those seen in the urban areas,'' which was especially obvious at the San Bernardino National Forest site, 90 km east of Los Angeles at an elevation of 1,384 meters (U.S. EPA, 2013a, p. 3–132). Thus, while the western sites that are influenced by upwind urban plumes may have increased cumulative seasonal values coincident with increased daily 8-hour peak O_3 concentrations, this analysis indicates that, in sites without such an urban influence (the eastern sites in this analysis), such a relationship does not occur (U.S. EPA, 2013a, section 3.6.3.2). Thus, the lack of such a relationship indicates that in some locations, O_3 air quality patterns can lead to elevated cumulative, seasonal O_3 exposures without the occurrence of elevated daily maximum 8-hour average O_3 concentrations (U.S. EPA, 2013a, section 3.6.3.2). Further, staff notes that the prevalence and geographic extent of such locations is unclear, since as in the last review, there continue to be relatively fewer monitors in the western U.S., including in high elevation remote sites. In considering the findings of this analysis, the PA additionally recognized, however, that the cumulative seasonal values for the eastern rural sites, where cumulative seasonal O_3 concentrations appear to be relatively less related to daily maximum 8-hour concentrations, are lower in general than those of the western, urban-influenced sites.

In addition to the focus study described in the ISA (U.S. EPA, 2013a, section 3.6.3.2), the PA considers additional analyses of air quality monitoring data. For example, Chapter 2 of the PA characterized recent monitoring data of O_3 air quality in rural areas. While approximately 80 percent of the O_3 monitoring network is urban focused, about 120 rural monitors are divided among CASTNET, NCore, and portable O_3 monitors (POMs) sites (U.S. EPA, 2014c, Chapter 2, pp. 2–2 to 2–3, Figure 2.1). Specifically, as stated in Chapter 2 of the PA, ''[a]lthough rural monitoring sites tend to be less directly affected by anthropogenic pollution sources than urban sites, rural sites can be affected by transport of O_3 or O_3 precursors from upwind urban areas and by local anthropogenic sources such as motor vehicles, power generation, biomass combustion, or oil and gas operations'' (U.S. EPA, 2013a, section 3.6.2.2). In addition, O_3 tends to persist longer in rural than in urban areas due to lower rates of chemical scavenging in non-urban environments. At higher elevations, increased O_3 concentrations can also result from stratospheric intrusions (U.S. EPA, 2013a, sections 3.4, 3.6.2.2). As a result, O_3 concentrations measured in some rural sites can be higher than those measured in nearby urban areas (U.S. EPA, 2013a, section 3.6.2.2) and the ISA concludes that ''cumulative exposures for humans and vegetation in rural areas can be substantial, and often higher than cumulative exposures in urban areas'' (U.S. EPA, 2013a, p. 3–120). These known differences between urban and rural sites suggest that there is the potential for an inconsistent relationship between 8-hour daily peak O_3 concentrations and cumulative, seasonal exposures in those areas. However, the PA also notes that reductions in NOx emissions that occur in urban areas to attain primary standards would also have the effect of reducing downwind, rural concentrations over the season (U.S. EPA, 2014c, section 6.4).

In addition, as was done in both the 1997 and 2008 reviews, the PA analyzed relationships between O_3 levels in terms of the current averaging time and form and a W126 cumulative form, based on recent air quality data. One analysis in the PA describes the W126 index values and current standard design values at each monitor for two periods: 2001–2003 and 2009–2011 (*e.g.,* U.S. EPA, 2014c, Appendix 2B, Figures 2B–2 and 2B–3). This shows that between the two periods, during which broad scale O_3

[223] This information and analyses were included in the second draft PA (U.S. EPA, 2014j), reviewed by CASAC in early 2014, and drafts of the ISA, reviewed by CASAC earlier in the review.

precursor emission reductions occurred, O_3 concentrations in terms of both metrics were reduced. There is a fairly strong, positive degree of correlation between the two metrics (U.S. EPA, 2014c, Appendix 2B).[224] Focusing only on the latter dataset (2009–2011), it can be seen that at monitors just meeting the current standard (three-year average fourth-highest daily maximum 8-hour average concentration equal to 0.075 ppm), W126 index values (in this case three-year averages) varied from less than 3 ppm-hrs to approximately 20 ppm-hrs (U.S. EPA, 2014c, Appendix 2B, Figure 2B–3b). At sites with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a potential alternative primary standard level of 70 ppb, three-year W126 index values were above 17 ppm-hrs at no monitors, above 15 ppm-hrs at one monitor, and above 13 ppm-hrs at 8 monitors in the West and Southwest NOAA climate regions. At sites with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a potential alternative primary standard level of 65 ppb, three-year W126 index values were above 11 ppm-hrs at no monitors, above 9 ppm-hrs at three monitors, and above 7 ppm-hrs at 9 monitors (distributed across five regions). The majority of these nine monitoring sites are located in the West and Southwest regions and include the states of Arizona, California, Colorado, Nevada, New Mexico, and Utah. At sites with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a potential alternative primary standard level of 60 ppb, three-year W126 index values were at or below 7 ppm-hrs at all monitors (U.S. EPA, 2014c, Figure 2B–3b).

Another analysis in Chapter 2 of the PA presents the data for sets of recent three-year periods back to 2006–2008 and indicates that among the counties with O_3 concentrations that met the current standard, the number of counties with three-year W126 index values above 15 ppm-hrs ranges from fewer than 10 to 24 (U.S. EPA, 2014c, Appendix 2B, Figure 2B–9). In general during this longer period, W126 index values above 15 ppm-hrs and meeting the current standard were predominantly in Southwest region. As the first analysis in Appendix 2B of the PA (for the 2001–2003 and 2009–2011 periods) indicates, monitors in the West and Southwest tend to have higher W126 index values relative to their design values than do monitors in other regions. This pattern is noteworthy because the Southwest region has a less dense monitoring network than regions in the eastern U.S. (see U.S. EPA, 2014c, Figure 2–1), so that the extent to which this pattern occurs throughout these regions is uncertain.

An additional air quality analysis was performed for this review that is documented in a technical memorandum (Wells, 2014). This analysis examines the relationships between O_3 levels in terms of the form and averaging time for the current standard (the ''4th max'' metric) and a three-year average, W126-based metric. The first part of the analyses focus on the air quality values for the most recent three-year period, 2011–2013. Based on this information, it can be seen that at monitors just meeting the current standard (three-year average fourth-highest daily maximum 8-hour average concentration equal to 0.075 ppm), W126 index values (in this case three-year averages) varied from less than 3 ppm-hrs to up to 23 ppm-hrs (Figure 5a). At sites with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a level of 70 ppb (566 monitors distributed across all regions of the U.S.), three-year W126 index values were above 17 ppm-hrs at no monitors, above 15 ppm-hrs at 4 monitors, and above 13 ppm-hrs at 16 monitors (1% of the monitors in full dataset and less than 3% in this group). These 16 monitors are located in the Southwest (15 monitors) and West North Central NOAA climate regions and include the states of Arizona, Colorado, New Mexico, Utah and Wyoming. At sites with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a level of 65 ppb (220 monitors distributed across all regions of the U.S.[225]), three-year W126 index values were above 11 ppm-hrs at no monitors, above 7 ppm-hrs at 15 monitors. These 15 monitoring sites are predominantly located in the West North Central and Southwest regions. At all sites with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a level of 60 ppb, three-year W126 index values were at or below 7 ppm-hrs (Wells, 2014, Figure 5b).

Further analysis in the technical memorandum focused on a comparison of monitors with a three-year average fourth-highest daily maximum 8-hour average concentration at or below a level of 70 ppb and a three-year W126 index values above 13 ppm-hrs for sets of three-year periods between 2001–2003 and 2011–2013 (Wells, 2014, Figure 8). This analysis found that the number of sites meeting 70 ppb while exceeding 13 ppm-hrs has remained relatively constant over the past decade, with these sites consistently being limited to a small number in the West and Southwest. In addition, the number of sites meeting both 70 ppb and 13 ppm-hrs has increased over time, while the number of sites exceeding both 70 ppb and 13 ppm-hrs has decreased by a similar amount.

The second part of the analysis in the technical memorandum focused on trends in the relationships between O_3 levels in terms of the 4th high metric and a three-year average W126 metric, starting with the 2001–2003 period and ending with the 2011–2013 period. Based on analysis of 729 monitors, trends in both the 4th high metric and the three-year average, W126 metric showed decreasing values between 2001–2003 and 2011–2013. In addition, the amount of year-to-year variability in the two metrics tended to decrease over time with decreasing O_3 concentrations, especially for the W126 metric. Most sites in the eastern U.S. and California saw large, widespread decreases in both the 4th high metric and the three-year average W126 metrics over the past decade as a result of regional NO_X control programs. In the inter-mountain west, where control programs have been more localized, the decreases observed in the 4th high metric and three-year average W126 metrics were typically much smaller in magnitude, with a small number of sites showing significant increases.

As part of this analysis, regional comparisons were included on the relative changes in the relationships between O_3 levels in terms of the 4th high metric and a three-year average W126 metric between the periods of 2001–2003 and 2011–2013. Figure 12 in the technical memorandum shows that a positive, linear relationship persists within each region between the changes in 4th high and three-year average W126 metrics. Nationally, the three-year average W126 metric decreased by approximately 0.7 ppm-hrs per unit ppb decrease in the 4th high metric. In addition, the Southwest and West regions, which have the greatest potential for sites to measure elevated cumulative, seasonal O_3 exposures without the occurrence of elevated daily maximum 8-hour average O_3 concentrations, exhibited the greatest

[224] Appendix 2B in the PA additionally observes that the program implemented for reducing precursor emissions, especially NOx, appears to have been an effective strategy for lowering both design values and W126 index values.

[225] This memo utilizes the same regional specifications as are used in the PA and WREA (*e.g.,* U.S. EPA, 2014c, Appendix 2B, Figure 2B–1).

response in W126 value change per unit change in 4th high metric (Wells, 2014, Table 6).

The technical memorandum concludes that the 4th high metric and a three-year average W126 metric are highly correlated, as are the relative changes in these two metrics over the past decade. In this way, the technical memorandum concludes that that future control programs designed to help meet a revised primary O_3 standard based on the three-year average of the 4th highest daily maximum 8-hour concentration are expected to also result in decreases in the values of a three-year average W126 metric.

The above information suggests that depending on the level for a standard of the current averaging time and form, the current form and averaging time of the secondary standard can be expected to achieve control of cumulative seasonal O_3 exposures, providing air quality that may meet specific three-year average W126 index values. As discussed above, we recognize limitations in the dataset and associated analyses, including those related to monitor coverage, which may contribute uncertainties to conclusions related to the relationships described. With respect to monitor coverage, the current O_3 monitoring network is urban focused, with fewer monitors in some parts of the country, particular rural areas of the southwestern and western U.S. Because of this, there are potential uncertainties in the extent to which the monitoring information discussed above represents air quality patterns and relationships that would occur in areas without monitors. There is some information suggesting that there is a potential for inconsistencies in the relationship between W126 measures of seasonal O_3 concentrations and the fourth highest peak O_3 concentrations assessed by the current standard averaging time and form, but the available data suggest that air quality in areas meeting a standard of the current form and averaging time with a level in the range of 65 to 70 ppb would also meet a three-year W126 index value falling in the range of 13 to 17 ppm-hrs, and that to the extent areas need to take action to attain a primary standard in the range of 65 to 70 ppb, those actions would also improve air quality as measured by the W126 metric.[226] To the extent to which the monitoring data can be expected to describe future relationships in air quality, we acknowledge potential uncertainties in specifying future air quality but note that these uncertainties are limited by the fact that the data analysis includes over a decade of O_3 measurements, with similar patterns and trends observed in air quality over this period of time.

5. Administrator's Proposed Conclusions

In considering what revisions to the secondary standard are appropriate, the Administrator has drawn on the ISA conclusions regarding the weight of the evidence for a range of welfare effects associated with O_3 in ambient air, and associated areas of uncertainty; quantitative risk and exposure analyses in the WREA for different adjusted air quality scenarios and associated limitations and uncertainties; staff evaluations of the evidence, exposure/risk information and air quality information in the PA; additional air quality analyses of relationships between air quality metrics based on form and averaging time of the current standards and a cumulative seasonal exposure index; and CASAC advice; and, public comments received thus far in the review.

As described in section IV.E.1 above, the Administrator concludes it is appropriate to continue to use O_3 as the indicator for a secondary standard intended to address adverse effects to public welfare associated with exposure to O_3 alone and in combination with related photochemical oxidants. In this review, no alternatives to O_3 have been advanced as being a more appropriate surrogate for ambient photochemical oxidants. Thus, as is the case for the primary standard (discussed above in section II.E.1), the Administrator proposes to continue to use O_3 as the indicator for a standard that is intended to address effects associated with exposure to O_3 alone and in combination with related photochemical oxidants. In so doing, the Administrator recognizes that measures leading to reductions in ecosystem exposures to O_3 would also be expected to reduce exposures to other photochemical oxidants.

The Administrator has next considered the array of information with regard to identifying policy options for a revised secondary standard for O_3 that in her judgment would provide appropriate protection for public welfare effects associated with O_3 in ambient air. This information includes ISA conclusions, WREA analysis findings, staff considerations and conclusions in the PA and CASAC advice, as well as the Administrator's conclusions in the last review, with regard to a biologically relevant exposure metric for O_3 vegetation-related effects. The information also includes PA conclusions and CASAC advice with regard to key aspects of the definition of such a metric, as summarized in section IV.E.2 and IV.E.3 above. Additionally, the Administrator has considered findings of staff evaluations in the PA with regard to potential impacts on vegetation and forested ecosystems associated with a range of values for such a metric and identified uncertainties and limitations of such information, as summarized in section IV.E.2 above. Additionally important to her deliberations here are findings of air quality analyses of relationships between the W126-based exposure metric and levels of a standard of the same form and averaging time as the current standards, as described in section IV.E.4 above. Based on consideration of this array of information, as described below, the Administrator has drawn conclusions with regard to policy options for a revised secondary standard. In drawing conclusions on such options, she recognizes that the Act does not require that NAAQS be set at zero-risk or background levels, but rather at levels that reduce risk sufficiently to protect public welfare from adverse effects.

As an initial matter, the Administrator recognizes the longstanding evidence, described in the ISA, of O_3 effects on vegetation and associated terrestrial ecosystems. Further, in reaching a proposed conclusion on the appropriate form and averaging time for a revised secondary standard that would provide increased protection against vegetation-related effects on public welfare, the Administrator takes note of the conclusions drawn in the ISA, the PA and by CASAC in this review that the scientific evidence continues to demonstrate the cumulative nature of O_3-induced plant effects and the need to give greater weight to higher concentrations, as summarized in sections IV.B.1, IV.D.1, IV.D.2, IV.E.2.a and IV.E.3 above. Based on these considerations, the Administrator concurs with the CASAC that a cumulative, seasonal, concentration-weighted exposure-based form and averaging time provides the most direct link between O_3 in ambient air and O_3-related effects on vegetation. The Administrator further concludes that in judging the extent of public welfare protection that might be afforded by a revised standard, it is appropriate to use

[226] EPA notes that areas can be expected to have air quality at least as good as that specified by the primary standard, so to the extent there are inconsistencies between fourth highest peak concentrations and W126 values such that some areas meeting a standard of 0.065 to 0.070 ppm might be well below the range of 13 to 17 ppm-hours, those inconsistencies are less relevant to consideration of the appropriate form and level for the secondary standard.

a cumulative, seasonal concentration-weighted metric.

In identifying a cumulative, seasonal, concentration-weighted metric for use in judging public welfare protection, the Administrator gives weight to the PA conclusions regarding consideration of a revised secondary standard in terms of the cumulative, seasonal, concentration-weighted form, the W126 index. As described in section IV.B.1 above, the ISA has recognized the strength of the W126 index in its weighting of potentially damaging O_3 concentrations that contributes to the advantages it offers over other weighted cumulative indices. The Administrator notes the PA conclusions regarding the W126 metric, specifically use of the three consecutive month period within the O_3 season with the maximum index value as the seasonal period over which to cumulate hourly O_3 exposures and the cumulation of daily exposures for the 12-hour period from 8:00 a.m. to 8:00 p.m. The Administrator additionally takes note of CASAC support for consideration of the W126 index defined in this way and concludes it is appropriate to use the cumulative seasonal W126-based metric derived in this way.

In further considering the PA conclusions regarding a revised secondary standard in terms of the W126 index, the Administrator takes note of considerations in the PA of a three-year or single-year evaluation period. Such considerations include the variability in ambient air O_3 concentrations from year to year, as well as variability and uncertainties related to environmental factors that influence the occurrence and magnitude of O_3-related effects. The Administrator additionally notes the PA observation of greater significance for effects associated with multiple-year exposures. Based on these and related considerations described in the PA (and summarized in section IV.E.2 above), the Administrator, in identifying a metric for use in judging public welfare protection afforded, agrees with the PA conclusion that it is appropriate to consider a form that averages W126 index values across three consecutive years, and to do so in conjunction with identification of levels for such a form that might be judged to provide the appropriate degree of public welfare protection from O_3 effects across multiple years. In so doing, the Administrator takes note of the ISA conclusions regarding the role of environmental factors in variability associated with effects of ambient air O_3 and the year-to-year variability commonly observed in such environmental factors. Further, the Administrator also recognizes uncertainties associated with determining the degree of vegetation impacts for annual effects that would be adverse to public welfare. Even in the case of annual crops, the assessment of public welfare significance is unclear for the reasons discussed below related to agricultural practices. The considerations identified here lead the Administrator to conclude it is appropriate to use an index averaged across three years.

In reaching this conclusion regarding a three-year average metric, the Administrator has considered CASAC comments that it favors a W126-based secondary standard with a single year form and that its recommended range of levels relates to such a form. The Administrator concurs with CASAC that it is important to consider impacts associated with a single year that may be of a magnitude concluded to represent an adverse effect on public welfare. The Administrator further concludes that such an occurrence can be addressed through use of a three-year average metric, chosen with consideration of the relevant factors. As noted above, the Administrator gives consideration to the variabilities, as well as the uncertainties, associated with single year and multiple year impacts. Based on all of these considerations, the Administrator recognizes greater confidence in judgments related to public welfare impacts based on a three-year average metric.

Thus, based on all of the above, the Administrator proposes, for purposes of judging the extent of public welfare protection that might be afforded by a revised standard and whether it meets the appropriate level of protection, to use the average W126 index value across three years, with each year's value identified as that for the three-month period yielding the highest seasonal value and with daily O_3 exposures within a three-month period cumulated for the 12-hour period from 8:00 a.m. to 8:00 p.m.

In reaching a conclusion on the appropriate range of W126 index values that describe the O_3 conditions expected to provide the requisite protection of public welfare, the Administrator has given careful consideration to the following: (1) The nature and degree of effects of O_3 to the public welfare, including what constitutes an adverse effect; (2) the strengths and limitations of the evidence that is available regarding known or anticipated adverse effects from cumulative, seasonal exposures, and its usefulness in informing selection of a proposed range; and (3) CASAC's views regarding a range of W126 levels appropriate to consider, as well as on the strength of the evidence and its adequacy to inform a range of levels. In this consideration, the Administrator recognizes that the choice of a range of W126 index values (and the form of the W126 index) that might be expected to provide protection of the public welfare from any known or anticipated adverse effects requires judgments about the interpretation of the evidence and other information, such as the quantitative analyses of air quality monitoring, exposure and risk, that neither overstates nor understates the strengths and limitations of the evidence and information nor the appropriate inferences to be drawn as to risks to public welfare. The CAA does not require that a secondary standard be protective of all effects associated with a pollutant in the ambient air but rather those considered adverse to the public welfare (as described in section IV.B.2 above). The Administrator additionally recognizes that there is not a bright line clearly directing the choice of a range of W126 index values and that the choice of what is appropriate is a public welfare policy judgment entrusted to the Administrator.

In determining the range of three-year average W126 index values that might be expected to provide the appropriate level of public welfare protection, the Administrator first considers the nature and degree of effects of O_3 on the public welfare. The Administrator recognizes that the significance to the public welfare of O_3-induced effects on sensitive vegetation growing within the U.S. can vary, depending on the nature of the effect, the intended use of the sensitive plants or ecosystems, and the types of environments in which the sensitive vegetation and ecosystems are located. Any given O_3-related effect on vegetation and ecosystems (*e.g.,* biomass loss, visible foliar injury), therefore, may be judged to have a different degree of impact on the public depending, for example, on whether that effect occurs in a Class I area, or a residential or commercial setting. The Administrator notes that such a distinction is supported by CASAC advice in this review. In her judgment, like those of the Administrator in the last review, it is appropriate that this variation in the significance of O_3-related vegetation effects should be taken into consideration in making judgments with regard to the level of ambient O_3 concentrations that is requisite to protect the public welfare from any known or anticipated adverse effects. As a result, the Administrator concludes that of those known and anticipated O_3-related vegetation and ecosystem effects

identified and discussed in this notice, particular significance should be ascribed to those that occur on sensitive species that are known to or are likely to occur in federally protected areas such as Class I areas [227] or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas.

Likewise, the Administrator also notes that the same known or anticipated O_3-induced effects occurring in other areas may call for less protection. For example, the maintenance of adequate agricultural crop yields is extremely important to the public welfare and is currently achieved through the application of intensive management practices. With respect to commercial production of commodities, the Administrator notes that judgments about the extent to which O_3-related effects on commercially managed vegetation are adverse from a public welfare perspective are particularly difficult to reach, given that the extensive management of such vegetation (which, as CASAC noted, may reduce yield variability) may also to some degree mitigate potential O_3-related effects. The management practices used on these lands are highly variable and are designed to achieve optimal yields, taking into consideration various environmental conditions. In addition, changes in yield of commercial crops and timber may affect producers and consumers differently, further complicating the question of assessing overall public welfare impacts. Thus, the Administrator concludes that agricultural crops do not have same need for additional protection from the NAAQS as forested ecosystems and, while research on agricultural crop species remains useful in illuminating mechanisms of action and physiological processes, information from this sector on O_3-induced effects is considered less useful in informing judgments on what level(s) would be sufficient but not more than necessary to protect the public welfare. The CASAC identified a crop RYL benchmark of 5% for the median species and indicated they found higher percentages unacceptably high. Although the Administrator has not drawn a conclusion with regard to this specific benchmark, the Administrator finds the public welfare impacts associated with crop yield loss to be a less important consideration in this review for the reasons discussed here, including the extensive management of crop yields and the dynamics of agricultural markets, and thus is not focusing on crop yield loss in selecting a revised standard. She notes, however, the PA finding that median species crop RYL estimates for W126 index values in the PA identified range (17 to 7 ppm-hrs) fall below the 5% benchmark emphasized by CASAC for this endpoint. The Administrator also notes that a standard revised to increase protection for forested ecosystems would also be expected to provide some increased protection for agricultural crops.

The Administrator also recognizes that O_3-related effects on sensitive vegetation can occur in other areas that have not been afforded special federal protections, ranging from effects on vegetation growing in managed city parks and residential or commercial settings, such as ornamentals used in urban/suburban landscaping or vegetation grown in land use categories that are heavily managed for commercial production of commodities such as timber. For vegetation used for residential or commercial ornamental purposes, the Administrator believes that there is not adequate information at this time to establish a secondary standard based specifically on impairment of these categories of vegetation, but notes that a secondary standard revised to provide protection for sensitive natural vegetation and ecosystems would likely also provide some degree of protection for such vegetation.

Based on the above, the Administrator finds that the type of information most useful in informing the selection of an appropriate range of protective levels is appropriately focused on information regarding exposures and responses of sensitive trees and other native species known or anticipated to occur in protected areas such as Class I areas or on lands set aside by States, Tribes and public interest groups to provide similar benefits to the public welfare, for residents on those lands, as well as visitors to those areas.

With regard to the available evidence, the Administrator finds the coherence and strength of the weight of evidence from the large body of available literature compelling. This evidence addresses a broad array of O_3-induced effects on a variety of tree species across a range of growth stages (*i.e.,* seedlings, saplings and mature trees) using diverse field-based (*e.g.,* free air, gradient and ambient) and OTC exposure methods. The Administrator gives particular attention to the effects related to native tree growth and productivity, recognizing their relationship to a range of ecosystem services, including forest and forest community composition.

With regard to selection of the values for use with the W126 index for the purpose of identifying a range of O_3 conditions expected to provide the appropriate level of protection from vegetation effects of particular concern, the Administrator, as an initial matter, takes note of the PA conclusion that, with regard to a target level of protection for a revised standard, it is appropriate to give consideration to a range of levels from 17 ppm-hrs to 7 ppm-hrs, expressed in terms of the W126 index averaged across three consecutive years. As summarized in section IV.E.2.b above, this PA conclusion draws heavily on considerations related to estimates of tree seedling growth impacts (in terms of relative biomass loss) associated with a range of W126-based index values developed from the robust E–R functions for 11 tree species. This conclusion also gives weight to CASAC comments as to an unacceptably high magnitude of relative biomass loss (6%) for the median species and a magnitude of median relative biomass loss on which to focus considerations (2%). The Administrator takes particular note of the CASAC view of a median species RBL of 6% as unacceptably high.

In considering the basis for the range of W126 index levels identified by the PA, for which 17 ppm-hrs is the upper end, the Administrator considers the CASAC advice, including their view that a 6% median tree seedling species RBL is unacceptably high, their consideration of Table 6–1 in the second draft PA which indicated such a RBL estimate for a W126 index value of 17 ppm-hrs, and their consequent lack of support for levels higher than 15 ppm-hrs (Frey, 2014c, p. iii; U.S. EPA 2014j, Table 6–1). As noted in section IV.E.3 above, revisions to this table in the final PA, made in consideration of CASAC comments have resulted in changes to the median species RBL estimates such that the median species RBL estimate for a W126 index value of 17 ppm-hrs in this table in the final PA (5.3%) is nearly identical to the median species estimate for 15 ppm-hrs (the value corresponding to the upper end of the CASAC-identified range) in the second draft PA (5.2%) (U.S. EPA, 2014c, Table 6–1; U.S. EPA, 2014j, Table 6–1).

[227] For example, the Wilderness Act of 1964 defines designated ''wilderness areas'' in part as areas ''protected and managed so as to preserve [their] natural conditions'' and requires that these areas ''shall be administered for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use and enjoyment as wilderness, and so as to provide for the protection of these areas [and] the preservation of their wilderness character.''16 U.S.C. 1131(a).

The Administrator additionally takes note of the PA observations that the number and proportion of individual species with RBL estimates at or below 2%, a benchmark given emphasis by CASAC, do not vary across W126 index values from 17 ppm-hrs down to 9 ppm-hrs (as seen in Table 8 above), providing little distinction with regard to the significance of growth impacts for exposures across this large portion of the PA range. The Administrator also notes the CASAC recommendation regarding a lowering of the level with consideration of a three-year average index; however, the Administrator's judgments on a three-year average index, as described above, focus on confidence in conclusions that might be drawn with regard to single as compared to multiple year impacts. For example, the Administrator, while recognizing the strength of the evidence with regard to quantitative characterization of O_3 effects on growth of tree seedlings and crops, in addition to noting the additional difficulties for assessing welfare impacts of crops, takes note of the uncertainty associated with drawing conclusions with regard to the extent to which small percent reductions in annual growth contribute to adverse effects on public welfare and the role of annual variability in environmental factors that affect plant responses to O_3. Moreover, as explained above, the Administrator concludes that concerns related to the possibility of a singly unusually damaging year can be addressed through use of a three-year average metric, chosen with consideration of the relevant factors. Accordingly, she judges it appropriate to include 17 ppm-hrs, without adjustment, in the range of three-year average W126 index values appropriate to consider in determining what secondary standard will provide air quality associated with the appropriate level of public welfare protection. She thus judges it appropriate to focus on a range for three-year average W126 levels with 17 ppm-hrs at the upper end. In so doing, she additionally notes CASAC's recognition that, within a scientifically appropriate range, the choice of levels is a public policy judgment by the Administrator.

In turning to consideration of the low end for the W126 index range, the Administrator considers the full range of W126 levels identified in the PA with regard to the evidence and exposure/risk-based information, and associated uncertainties, identified in the PA, as well as CASAC advice. The Administrator notes the CASAC policy view regarding protection provided for trees and associated ecosystem services from a W126 index value of 7 ppm-hrs, which is based on the W126 index value for which the median species estimate falls below 2% RBL. The Administrator recognizes, however, as noted above, the greater uncertainty associated with the extent to which estimates of benefits in terms of ecosystem services and reduced effects on vegetation at lower O_3 exposures might be judged significant to the public welfare.

The Administrator additionally notes the results of the EPA's quantitative exposure and risk assessments for the air quality scenarios for W126 levels at and below 11 ppm-hrs, including the relatively small additional benefits and increased uncertainty with the ecosystem services estimates in these lower W126 scenarios. With regard to the PA evaluation of RBL estimates, the Administrator, while noting the PA observations of similarity in the number of species with less than 2% RBL across the W126 range from 17 to 9 ppm-hrs, as stated above, additionally notes PA observations of a similar number of studied species with RBL estimates below 5% for W126 index values of 13 and 11 ppm-hrs. Thus, to the extent that weight is given to the importance of 5% RBL for individual species, both W126 index values are observed to provide RBL estimates below this benchmark.

With regard to considerations of O_3 effects beyond biomass loss in tree seedlings, the Administrator takes note of the lack of new quantitative E–R relationships for larger trees growing in the field that would help inform consideration of a standard level within the lower part of PA range. Thus, the Administrator recognizes that important uncertainties remain in interpreting the quantitative O_3-related growth effects for tree seedlings assessed in OTC studies for the purpose of characterizing long-term growth effects, and other more subtle but important effects on sensitive tree species, natural forests, and forested ecosystems in the broader context of protection of public welfare. Additionally, while the Administrator notes that there is evidence that O_3-related visible foliar injury can occur at such lower levels (below a W126 index value of 13 ppm-hrs), she recognizes, as summarized in sections IV.C.3.c and IV.D.1 above, the significant challenges in judging the extent to which such effects should be considered adverse to public welfare, in light of the variability and the lack of clear quantitative relationship with other effects on vegetation, as well as the lack of established criteria or objectives that might inform consideration of potential public welfare impacts related to this vegetation effect.

Thus, in the Administrator's judgment, focus on a three-year average W126 index value below 13 ppm-hrs would not give sufficient attention to the important uncertainties and limitations inherent in the currently available scientific evidence and in the quantitative assessments conducted for the current review. Taking into account the uncertainties that remain in interpreting the evidence, the Administrator observes that the likelihood of obtaining benefits to public welfare decreases with a standard set below a level of 13 ppm-hrs, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to reduce adverse impacts to public welfare increases.

Based on the above considerations and based on the entire body of evidence and information currently available, the Administrator identifies the range of three-year average W126 index values extending from 13 to 17 ppm-hrs as appropriate to consider in identifying the ambient O_3 concentrations that would provide the appropriate level of public welfare protection. In so doing, the Administrator notes CASAC recognition that a three-year average W126 level of 13 ppm-hrs may be appropriate depending on consideration of year-to-year variability and policy considerations. Thus, based on the discussion above, and with consideration of CASAC advice on these issues, the Administrator proposes that ambient O_3 concentrations resulting in cumulative seasonal O_3 exposures of a level within the range from 13 ppm-hrs to 17 ppm-hrs, in terms of a W126 index averaged across three consecutive years, would provide the requisite protection against known or anticipated adverse effects to the public welfare. The EPA solicits comments on levels within this range.

The Administrator next turns to consideration of policy options for a revised secondary standard that would provide this level of protection. The Administrator takes note of staff conclusions that it is appropriate to consider a revised secondary standard in terms of the cumulative, seasonal, concentration-weighted form, the W126 index. Further, she gives extensive consideration to CASAC advice to set such a secondary standard. Such a standard, as mentioned above, would be directly linked to O_3 exposures to which vegetation are most responsive and thus might be expected to provide some

confidence that such exposures of concern would be controlled.

In considering different policy options for a revised secondary standard, the Administrator finds it useful to consider what can be concluded from the available information with regard to relationships between air quality characterized in terms of the current form and averaging time and also in terms of the W126 metric. She has considered particularly what such analyses and relationships indicate with regard to the extent to which W126-based O_3 concentrations may be controlled by a revised secondary standard set identical to a revised primary standard (in the range identified in section II.F above). In so doing, she considers the air quality analyses in the PA and also the analyses of more recent air quality data summarized in the EPA technical memo (described in section IV.E.4 above), focusing particularly on analyses examining the W126-based O_3 exposure achieved in locations found to meet potential alternative standards within the range of primary standards proposed in section II.F above.

Findings from these analyses of recent O_3 measurements and trends in the relationship between the current standard and the W126 metrics were substantially similar for the various time periods examined over the past decade. There is some information suggesting that there is a potential for inconsistencies in the relationship between W126 measures of seasonal O_3 concentrations and the fourth highest peak O_3 concentrations assessed by the current standard averaging time and form, but the available data suggest that air quality in areas meeting a primary standard in the range of 65 to 70 ppb would also meet a three-year W126 index value falling in the range of 13 to 17 ppm-hrs, and that to the extent areas need to take action to attain a standard in the range of 0.065 to 0.070 ppm, those actions would also improve air quality as measured by the W126 metric. The Administrator also recognizes that the relatively lesser density of monitors in rural areas, including in areas of the West and Southwest NOAA climatic regions currently meeting the current standard where O_3 W126 index values are generally higher, makes uncertain the degree to which a revised level for the current standard would provide the appropriate degree of protection for vegetation-related effects on public welfare in these areas. The Administrator takes note of the PA finding, referenced in section IV.D.3 above, that reductions in NO_X emissions that occur in urban areas to attain primary standards would also have the effect of reducing downwind, rural concentrations over the season. Thus, while the potential for underprotection may exist, depending on the specific levels chosen, the extent of such areas and of such a risk is not clear.

Based on the most recent period of monitoring data, the Administrator notes that in all areas in which the O_3 concentrations would have met a primary standard with a revised level of 70 ppb (which includes over 500 monitors distributed across all regions of U.S), the three-year average W126 index values are at or below 17 ppm-hrs. In the same areas, only 16 monitors (or less than 3% of all monitors in this group, all but one of which is located in the Southwest region) had three-year average W126 index values above 13 ppm-hrs. She further notes that in all areas in which the O_3 concentrations would have met a primary standard with a revised level of 65 ppb (which includes 220 monitors distributed across all regions of U.S), the three-year average W126 index values are at or below 13 ppm-hrs.

In considering these findings regarding cumulative seasonal O_3 exposures in areas that would have met a primary standard with a revised level within the proposed range, the Administrator also takes note of the high correlation observed between the design value for the current secondary (and primary) standard and values for the three-year average, W126 metric, as well as the high correlation in the relative changes in these two metrics based on air quality analyses of O_3 measurements from over the past decade. This finding supports a conclusion that the air quality analyses indicate that future control programs designed to reduce O_3 concentrations to help meet a revised primary O_3 standard that retains the current form and averaging time (three-year average of the 4th highest daily maximum 8-hour concentration) would also be expected to result in reductions in three-year average, W126 index values. Further, she notes the conclusion from the air quality analysis that the Southwest and West regions, which have the greatest potential for sites to measure elevated cumulative, seasonal O_3 exposures without the occurrence of elevated daily maximum 8-hour average O_3 concentrations, exhibited the greatest response in W126 index value change per unit change in metric based on the current standard form and averaging time. While recognizing the limitations of such analyses in projections of future air quality patterns, the Administrator also notes that the time period over which the analyses focused involved emissions control programs to achieve O_3 reductions such that their findings would be expected to be informative of further similar control activities, such as those to meet a revised standard with a lower level, in the future.

Based on the findings from these analyses, the Administrator finds it appropriate to consider the policy option of retaining the form and averaging time of the current secondary standard and revising the level to within the range of 65 to 70 ppb. In such consideration, the Administrator first notes her proposed conclusion that the requisite protection from known or anticipated adverse effects to public welfare may be achieved by cumulative, seasonal, concentration-weighted O_3 concentrations characterized in terms of a W126 index value that falls within the range from 13 to 17 ppm-hrs. Her final decision on the W126 index value in this range that affords the requisite protection will be based on a series of judgments, as described above. Given the focus on tree seedling growth effects in identifying this range, such judgments will include the weight to give the evidence of specific vegetation-related effects estimated to result from W126 index values within this range, including the objectives for consideration of tree species biomass loss estimates in relationship to identified benchmarks (*e.g.,* median species RBL of 2% and greater), the weight to give associated uncertainties, including those related to the variability in occurrence of such effects in forested areas, the associated ecosystem services including those of particular public welfare significance, and judgments on the extent to which such effects in forested areas may be considered adverse to public welfare. This final decision will also take into account judgments with regard to the weight to give the evidence and quantitative analyses, and associated uncertainties, related to other effects of O_3 (summarized in sections IV.C, IV.D.1 and IV.E.2 above), particularly including those for which the ISA concludes causal or likely causal relationships with O_3 exposures. As noted above, a standard that provides the appropriate level of protection for growth effects would also be expected to provide additional protection for other effects including visible foliar injury, crops and carbon storage.

The Administrator notes that based on the above analyses, the proposed range of levels for a revised primary standard provide air quality, in terms of three-year average W126 index values, of a

range at or below the range which the Administrator has identified for consideration with regard to the requisite public welfare protection. Thus, depending on final judgments on revisions to the primary standard and the requisite protection for the secondary standard, a revised secondary standard identical to the revised primary standard may provide sufficient protection for public welfare. Therefore, the Administrator proposes to retain the current averaging time and form of the secondary standard and revise the level to within the range of 65 to 70 ppb.

In reaching such a conclusion, the Administrator recognizes that such a strengthening of the secondary standard would be expected to provide significant additional protection for public welfare, including effects related to vegetation and associated ecosystem services (and others discussed above), over that afforded by the current secondary standard.

Thus, based on her consideration of the full range of information as described above, the Administrator judges that ambient O_3 concentrations in terms of a three-year average W126 index value within the range extending from 13 ppm-hrs to 17 ppm-hrs would provide requisite public welfare protection. She further judges that it would be appropriate to achieve that level of air quality by retaining the existing averaging time and form, and revising the level to within the range of 65 to 70 ppb. In recognition of CASAC's recommendation and the PA conclusion with regard to a distinct secondary standard, the Administrator additionally solicits comment on the policy option of revising the form and averaging time for the secondary standard to a W126 index value, averaged across three years, with each year's value identified as that for the three-month period yielding the highest seasonal value and with daily O_3 exposures within a three-month period cumulated for the 12-hour period from 8:00 a.m. to 8:00 p.m., and a level within the range from 13 ppm-hrs to 17 ppm-hrs.

F. Proposed Decision on the Secondary Standard

The Administrator proposes to revise the level of the current secondary standard within the range of 0.065 to 0.070 ppm. The EPA solicits comments on this proposed revision of the secondary standard. Further, the EPA solicits comments on the proposed conclusion that air quality in terms of a W126 index value, averaged across three consecutive years, within the range of 13 ppm-hrs to 17 ppm-hrs would provide requisite protection against known or anticipated adverse effects to the public welfare. Additionally, the EPA solicits comments on alternative values for a three-year average W126 index for such a purpose within the range extending below 13 ppm-hrs down to 7 ppm-hrs.

The EPA also solicits comments on the alternative approach of revising the secondary standard to a cumulative, seasonal, concentration-weighted form, the W126 index based on the three consecutive month period within the O_3 season with the maximum index value, with daily exposures cumulated for the 12-hour period from 8:00am to 8:00pm and with a form that averages seasonal W126 values across three consecutive years and a level within the range of 13 to 17 ppm-hrs. The EPA additionally solicits comments on such a distinct secondary standard with a level within the range extending below 13 ppm-hrs down to 7 ppm-hrs. Further, the EPA solicits comments on retaining the current secondary standard without revision, along with the alternative views of the evidence that would support retaining the current standard.

V. Appendix U: Interpretation of the Primary and Secondary NAAQS for O_3

A. Background

The EPA is proposing to create Appendix U to 40 CFR part 50 to reflect the proposed revisions to the primary and secondary NAAQS for O_3 discussed in previous sections of this preamble. The proposed Appendix U explains the computations necessary for determining when the proposed primary and secondary O_3 NAAQS are met at an ambient air quality monitoring site, similar to Appendix P to 40 CFR part 50 which deals with interpretation of the O_3 NAAQS promulgated in 2008. Specifically, the proposed Appendix U addresses data selection requirements (section V.B), data reporting and data handling requirements (section V.C), and data completeness requirements. The EPA is proposing to maintain the data completeness requirements from the previous O_3 NAAQS.

Given that the EPA is soliciting public comment on a distinct secondary standard based on the W126 metric, section V.D of this preamble contains a discussion of additional data handling requirements that would be adopted in Appendix U in the event that the Administrator decides to set a distinct secondary standard based on public comments received.

The proposed Appendix U also provides specific requirements for the handling of data affected by exceptional events in accordance with 40 CFR 50.14. Section V.E of this preamble addresses O_3-specific deadlines related to the flagging and submission of demonstrations for exceptional event data for the proposed O_3 NAAQS.

B. Data Selection Requirements

The EPA is proposing to clarify which data are to be used in comparisons with the NAAQS. First, the EPA proposes to maintain the existing regulatory requirements that only O_3 data collected by a federal reference method specified in Appendix D to 40 CFR part 50, or an equivalent method designated in accordance with 40 CFR part 53, and meeting all applicable monitoring requirements listed in 40 CFR part 58, are eligible for comparison to the proposed O_3 NAAQS.

Second, the EPA is proposing in Appendix U that O_3 design values are to be calculated on a site-level basis. Past practice has been to calculate a design value for each individual O_3 monitor. However, this practice could be viewed as inconsistent with the stated purpose of the previous O_3 data handling appendix, which is to determine ''whether the national 8-hour primary and secondary ambient air quality standards for ozone (O_3) specified in § 50.15 are met at an ambient O_3 air quality monitoring *site.''* (40 CFR part 50, Appendix P, section 1 (emphasis added)). Given the level of consistency in the measurement data obtained across the various federal reference and equivalent O_3 monitoring instruments currently in operation (U.S. EPA, 2013a, section 3.5.2.1), the EPA believes that it would be appropriate to combine data across O_3 monitors operating at the same site. Therefore, the EPA is proposing an analytic approach for combining data collected from multiple O_3 monitors at a site in order to obtain a single set of hourly O_3 concentration data for each site.

The proposed approach allows the monitoring agencies to designate one monitor as the ''primary monitor'' for each site. In the absence of a primary monitor designation, the primary monitor would default to the monitor with the most complete hourly dataset in each year. Once a primary monitor has been determined for the site, missing hourly O_3 concentrations for the primary monitor would be substituted from any other monitors at the site. In the event of three or more monitors operating at the same site, missing hourly O_3 concentrations for the primary monitor would be substituted with hourly values averaged across the other monitors. The EPA notes that at the time of this proposal, there were approximately 20 sites operating two

monitors simultaneously, and no O_3 sites operating three or more monitors simultaneously. This proposed approach for combining data across monitors at a site is consistent with the existing approach described in Appendix N to Part 50 for the $PM_{2.5}$ NAAQS. The EPA invites public comment on the scientific validity of combining data across O_3 monitors, and the merits of the proposed approach for combining data across multiple O_3 monitors at a site.

Third, the EPA proposes to maintain the existing practice of combining data from nearby monitoring sites in order to determine a valid design value, known as a ''site combination''. Site combinations typically involve situations where sites have been replaced or relocated a short distance away, and the monitoring agency wishes to combine the data from the two sites in order to maintain a continuous data record. The EPA regional offices have approved over 100 site combinations for O_3 since the promulgation of the 1997 O_3 NAAQS. The EPA has maintained records of approved site combinations, but these records are not easily accessible by the public.

The EPA proposes to replace the current procedure for approving O_3 site combinations with a more formal procedure in Appendix U, which would allow states to submit site combination requests to the appropriate Regional Administrator. Site combinations may be approved by the Regional Administrator, after he or she has determined that the measured air quality concentrations do not differ substantially between the two sites. In order to make this determination, the Regional Administrator may request additional information from the states, including detailed information on the locations and distance between the two sites, levels of ambient concentrations measured at the two sites, and local emissions or meteorology data.

In order to improve transparency, the EPA will make records of all approved site combinations available in their Air Quality System (AQS) database, and will update design value calculations in AQS so that approved site combinations are implemented. The EPA invites public comment on the merits of the proposed process for approving site combinations in order to obtain valid design values for the O_3 NAAQS.

C. Data Reporting and Data Handling Requirements

The EPA is proposing to maintain the requirement that hourly O_3 concentration data be reported in parts per million (ppm) to three decimal places. Any decimal digits reported beyond three decimal digits will be truncated, consistent with past practice (40 CFR part 50, Appendix P, section 2.1) and the typical measurement uncertainty associated with most O_3 monitoring instruments. The proposed Appendix U clarifies that hourly O_3 concentrations are to be reported in Local Standard Time (LST), consistent with how the values are currently stored in AQS.

The EPA is proposing to maintain the existing procedures for calculating moving 8-hour averages from the hourly O_3 data (40 CFR part 50, Appendix P, section 2.1), with one minor exception. In instances where fewer than six hourly O_3 concentrations are available during an 8-hour period (*i.e.* less than 75% completeness), the EPA is proposing to substitute zero (*i.e.* 0.000 ppm) instead of one half of the O_3 monitoring instrument's minimum detectable limit (MDL) for the missing concentration values to determine if the resulting 8-hour average is greater than the level of the NAAQS. The purpose of this ''data substitution test'' is to identify any 8-hour periods that do not meet the requirements for a valid 8-hour average, but have reported concentrations that are so high that the NAAQS is exceeded even when substituting low values for the missing concentrations. The EPA believes that a constant substitution value of zero is preferable to 1/2 MDL, which may vary across O_3 monitoring instruments. The MDL value for most O_3 monitoring instruments is 0.005 ppm, and the 1/2 MDL value is 0.002 ppm (with truncation); thus, in practice, the difference is slight. The EPA notes that a value of zero micrograms per cubic meter (ug/m^3) is used in data substitution tests for 24-hour average $PM_{2.5}$ concentrations, as specified in Appendix N to 40 CFR part 50. The EPA invites public comment on the merits of using zero instead of 1/2 MDL for the 8-hour average data substitution test.

The EPA is proposing new procedures for determining daily maximum 8-hour average O_3 concentrations. Past practice allows for daily maximum 8-hour average O_3 concentrations from two consecutive days to have some hours in common (40 CFR part 50, Appendix P, section 2.1). One implication of this is that an O_3 site may be counted as having exceeded the NAAQS on two distinct days based on two 8-hour periods having up to 7 hours in common. Theoretically, this could result in an annual fourth-highest value greater than the NAAQS based on high overnight O_3 concentrations occurring only twice during the year.

The EPA performed an analysis based on ambient O_3 concentration data from 2004 to 2013 (Wells, 2014b), which showed that at least one instance of overlapping daily maximum 8-hour averages occurred at 99.5% of O_3 sites during that time period. Overlapping daily maximum 8-hour averages were infrequent at most sites, but in some cases, these values occurred quite regularly (up to 60 times per year). Overlapping daily maximum 8-hour averages contributed to additional exceedances of the proposed O_3 NAAQS at 14% of sites for a level of 0.070 ppm, and at 23% of sites for a level of 0.065 ppm. In addition, 8% of sites had overlapping daily maximum 8-hour averages which contributed to a higher annual fourth-highest daily maximum value in one or more years. Finally, the analysis showed that O_3 sites located in non-urban areas affected by long-range transport, especially those sites at higher elevations, were most likely to have additional exceedances of the proposed O_3 NAAQS due to the occurrence of overlapping daily maximum 8-hour averages.

Based on this analysis, the EPA initially concludes that overlapping daily maximum 8-hour averages are more likely to contribute to additional exceedances of the O_3 NAAQS as the level of the standard is lowered. Therefore, the EPA is proposing a new procedure for determining daily maximum 8-hour average O_3 concentrations for the proposed NAAQS that is based on 17 consecutive 8-hour periods in each day, beginning with the 8-hour period from 7:00 a.m. to 3:00 p.m., and ending with the 8-hour period from 11:00 p.m. to 7:00 a.m. Given that 8-hour averages are stored in the beginning hour of each period, this corresponds to the 8-hour averages from 7:00 a.m. to 11:00 p.m.

The rationale for the proposed approach is twofold. First, it avoids any possibility of ''double counting'' exceedances of the NAAQS based on 8-hour periods with one or more hours in common, while continuing to make use of all of the hourly concentration data, and keeping the calculations simple and straightforward. Second, it is more consistent with the physical processes involved in the formation and transport of ground-level O_3. Specifically, the chemical reactions involved in the formation of new ground-level O_3 require sunlight. Therefore, it is appropriate to begin the ''O_3 day'' at sunrise, which for simplicity is assumed to be 7:00 a.m. LST. Similarly, any daily maximum 8-hour averages occurring after sunset are assumed to be caused by transport of O_3 molecules which

originated before sunset. Therefore, it is appropriate to end the ''O_3 day'' with the 8-hour period beginning at 11:00 p.m. and ending at 7:00 a.m.

In order to accommodate the above proposed approach to the hours considered in an ''O_3 day'', the EPA is also proposing to modify the requirement for determining whether a daily maximum 8-hour average O_3 concentration is valid for assessing compliance with the NAAQS (40 CFR part 50, Appendix P, section 2.1). The proposed Appendix U requires valid 8-hour averages for 13 of the 17 8-hour periods in a day in order to determine a valid daily maximum value. The requirement of 13 valid 8-hour averages was chosen because 13/17 is the smallest ratio greater than 75%, which is consistent with the long standing requirement of 75% data completeness for daily and annual NAAQS-related statistics. In addition, the EPA is proposing to maintain the existing provision allowing daily maximum 8-hour averages greater than the level of the NAAQS to be considered valid (40 CFR part 50, Appendix P, section 2.1). The EPA invites public comment on the merits of the proposed procedure for determining daily maximum 8-hour average O_3 concentrations, and the merits of the proposed daily validity criteria.

Finally, the EPA has included additional language in the proposed Appendix U codifying existing data handling procedures for the previous O_3 NAAQS. First, the proposed Appendix U maintains the provision that hourly O_3 concentrations approved under 40 CFR 50.14 as having been affected by exceptional events are to be counted as missing or unavailable when calculating 8-hour averages, and that these concentrations are to be included when determining whether the daily validity criteria have been met for a given day. Effectively, this means that it is possible for an 8-hour period affected by exceptional events to lack sufficient data to determine an 8-hour average, yet the 8-hour period may still be counted toward meeting the daily validity criteria. Second, the proposed Appendix U maintains the existing practice of including monitored days outside of the O_3 monitoring season when determining the annual fourth-highest daily maximum value. Finally, the proposed Appendix U maintains the existing practice of using only daily maximum 8-hour average values for days where the daily validity criteria have been met when determining the annual fourth-highest daily maximum value.

D. Considerations for the Possibility of a Distinct Secondary Standard

Given that the EPA is soliciting public comment on setting a distinct secondary O_3 NAAQS based on the W126 index, the EPA is including a discussion on the data handling requirements for a distinct secondary standard. In the event that the Administrator decides to set a distinct secondary O_3 standard based on the W126 index, the EPA will adopt data handling requirements for the secondary standard similar to those proposed during the reconsideration of the 2008 O_3 NAAQS in 2010 (see 75 FR 3049–3052, January 19, 2010).

Two changes would need to be made to the data handling provisions for the secondary standard proposed in 2010 in order to provide consistency with what the EPA is proposing for the primary standard in Appendix U. First, the secondary standard design value (*i.e.* the 3-year average of the annual W126 index) would be truncated after the decimal point, instead of being rounded to the nearest whole number. Second, paragraph 4(c)(ii) would be modified to read:

''If one or more months during the ozone monitoring seasons of three consecutive years has less than 75% data completeness, the three years shall nevertheless be used in the computation of a valid design value for the site, if, after adjusting the monthly W126 index values for the months with less than 75% data completeness by a factor of 4/3, the resulting design value is greater than the level of the standard.''

E. Exceptional Events Information Submission Schedule

States [228] are responsible for identifying air quality data that they believe warrant special consideration, including data affected by exceptional events. States identify such data by flagging (making a notation in a designated field in the electronic data record) specific values in the AQS database. States flag the data and submit supporting documentation showing that the data have been affected by exceptional events if they wish the EPA to consider excluding the data in regulatory decisions, including determining whether or not an area is attaining the proposed revised O_3 NAAQS, if a different standard is finalized.

All states and areas of Indian country that include areas that could exceed or contribute to an exceedance of any revised O_3 NAAQS in a nearby area and could therefore be designated as nonattainment have the potential to be affected by this rulemaking. Therefore, this action applies to all states; to local air quality agencies to which a state has delegated relevant responsibilities for air quality management including air quality monitoring and data analysis; and to tribal air quality agencies, where appropriate.

The ''Treatment of Data Influenced by Exceptional Events; Final Rule'' (72 FR 13560, March 22, 2007), known as the Exceptional Events Rule and codified at 40 CFR 50.1, 50.14 and 51.930, contains generic deadlines for a state to submit to the EPA specified information about exceptional events and associated air pollutant concentration data. Under this generic flagging schedule in 40 CFR 50.14(c)(2)(iii), a state must initially notify the EPA that data have been affected by an event by July 1 of the calendar year following the year in which the event occurred. This is done by flagging the data in AQS and providing an initial event description. According to the generic demonstration schedule in 40 CFR 50.14(c)(3)(i), the state must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within 3 years after the quarter in which the data were collected. This section of the regulation also states that if the EPA must make a regulatory decision based on the data, the state must submit all information to the EPA no later than 1 year before the decision is to be made.

These generic deadlines in the Exceptional Events Rule apply to data influencing redesignation efforts or other regulatory decisions made by the EPA after the EPA promulgates initial area designations for a new or revised NAAQS. However, these same generic deadlines in the Exceptional Events Rule may not work well with the timing of the initial area designation process and schedule under a new or revised NAAQS. Until the EPA promulgates the level and form of the NAAQS, a state does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met for a given event. In some cases, the generic deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the EPA promulgates the new or revised NAAQS. This scheduling constraint could result in the EPA's being unable to consider whether an exceptional event has affected the data relied on for initial area designations and further result in an area being designated nonattainment based on data

[228] References to ''state'' are meant to include state, local and tribal agencies responsible for preparing and submitting exceptional event documentation as identified in the Exceptional Events Rule (72 FR 13560, March 22, 2007).

that might have been excluded as having been influenced by an exceptional event if the EPA had been able to consider it during the designation process. For this reason, the EPA has historically undertaken rulemaking as part of the NAAQS promulgation process to adjust the generic deadlines in sections 50.14(c)(2)(iii) and 50.14(c)(3)(i) of the Exceptional Events Rule to accommodate the initial area designation process and schedule under a new or revised NAAQS.

The Exceptional Events Rule at section 50.14(c)(2)(vi) indicates ''when EPA sets a NAAQS for a new pollutant or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging exceptional event data, providing initial data descriptions and providing detailed data documentation in AQS for the initial designations of areas for those NAAQS.'' The EPA intends to issue its final action promulgating a revised O_3 NAAQS or determine that it is not necessary to do so in October 2015.

The CAA provides requirements regarding the schedule for initial area designations. Section 107(d)(1) of the CAA states that, ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall . . . submit to the Administrator a list of all areas (or portions thereof) in the State, designating . . . '' those areas as nonattainment, attainment, or unclassifiable.[229] No later than 120 days prior to promulgating designations, the EPA is required to notify states of any intended modifications to their designation recommendations as the EPA may deem necessary. Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) . . . as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.'' As described in more detail in section VII.C of this proposal, the EPA intends to complete designations for any revised O_3 NAAQS promulgated in 2015 following the standard 2-year process. The EPA is required by Court Order to take final action for this O_3 NAAQS review no later than October 1, 2015. The EPA does not intend to establish a date earlier than the 1 year submission period provided in CAA section 107(d)(4); thus, state Governors (and tribes, if they choose) would be required to submit their initial designation recommendations for any revised NAAQS no later than 1 year after promulgation (*i.e.,* by October 1, 2016, if the EPA promulgates a revised NAAQS on October 1, 2015). State Governors (and tribes, if they choose) would likely use air quality data from the years 2013 to 2015 as the basis for their recommendations. The EPA would notify states and tribes of intended modifications to their recommendations no later than June 2017 and the EPA would promulgate initial designations for any revised NAAQS in October 2017. We anticipate that the EPA's notification of intended modifications and the final designations would be based on air quality data from the years 2014 to 2016, because air quality data from 2016 is required to be certified by the state no later than May 1, 2017, and thus would be available for consideration for purposes of initial area designations by October 2017.

As indicated above, and as explained in additional detail in section VII.C of this preamble, section 107(d)(1)(B) of the CAA allows the Administrator to extend the designations schedule for up to 1 year in the event the Administrator has insufficient information to promulgate the designations for a newly promulgated NAAQS. If the EPA were to determine that it is necessary to extend the schedule for designating areas for a revised O_3 NAAQS (promulgation in October 2015) from 2017 to 2018, then it is possible that air quality data from 2017 could be considered for designations. This could raise concerns about whether influences from exceptional events in 2017 could be investigated and submitted by the state and reviewed by the EPA in sufficient time for consideration during the designation process.

For purposes of initial designations, where the EPA considers the most recent air quality monitoring data in a relatively quick timeframe, the EPA is proposing revisions to the flagging and data submission schedule in 40 CFR 50.14 applicable to the initial area designations process. The proposed exceptional events schedule is based on following a standard 2 year designation process. However, because the CAA also provides for a 3-year process in the event the Administrator has insufficient information to promulgate the designations for a newly promulgated NAAQS within 2 years and provides for the promulgation of designations as ''expeditiously as practicable,'' which could include accelerating the designations schedule ahead of the 2-year schedule, the proposed exceptional event schedule also includes provisions for both an accelerated designations process and a 3-year process. If the EPA were to pursue a designations schedule other than a 2- or 3-year process, the EPA would notify the state Governors of the intended date for final designations through notification letters, guidance and/or **Federal Register** notices.

These proposed revised exceptional event scheduling provisions would, if promulgated, apply to submission of information supporting claimed exceptional events affecting pollutant data for initial area designations under any new or revised NAAQS, including any revised O_3 NAAQS promulgated in October 2015. The general data flagging deadlines in the Exceptional Events Rule at 40 CFR 50.14(c)(2)(iii) and the general schedule for submission of demonstrations at 40 CFR 50.14(c)(3)(i) would continue to apply to regulatory decisions other than those related to the initial area designations process under a new or revised NAAQS. The EPA believes these proposed revisions to the exceptional events scheduling provisions will provide adequate time for states to determine whether data have been influenced by an exceptional event, to notify the EPA by flagging the relevant data and providing an initial description in AQS, and to submit documentation to support claims for exceptional events.

Therefore, using the authority provided in CAA section 319(b)(2), the EPA proposes to modify the schedule for data flagging and submission of demonstrations for exceptional events data considered for initial area designations by replacing the deadlines and information in Table 1 in 40 CFR 50.14 with the deadlines and information presented in Table 9. The EPA is also providing Table 10 to illustrate how the proposed schedule might apply to the designations process for any revised O_3 NAAQS promulgated in October 2015 or to designations processes for future new or revised NAAQS. The EPA invites comment on these proposed changes, shown in Table 9, to the exceptional event data flagging and documentation submission deadlines for future new or revised

[229] While the CAA says ''designating'' with respect to the Governor's letter, in the full context of the CAA section it is clear that the Governor actually makes a recommendation.

NAAQS, including any revised O_3 NAAQS promulgated in 2015.

TABLE 9—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN INITIAL AREA DESIGNATIONS

Exceptional event/regulatory action	Exceptional event deadline schedule [d]
Exceptional event data flagging and initial description deadline for data years 1, 2 and 3 [a].	If state and tribal initial designation recommendations for the new/revised NAAQS are due August through January, then the flagging and initial description deadline will be the July 1 prior to the recommendation deadline. If state and tribal recommendations for the new/revised NAAQS are due February through July, then the flagging and initial description deadline will be the January 1 prior to the recommendation deadline.
Exceptional event demonstration submittal deadline for data years 1, 2 and 3 [a].	No later than the date that state and tribal recommendations are due to EPA.
Exceptional event data flagging, initial description, and exceptional event demonstration submittal deadline for data year 4 [b] and potential data year 5 [c].	By the last day of the month that is 1 year and 7 months after promulgation of a new or revised NAAQS, unless either option a or b applies. a. If the EPA follows a 3-year designation schedule, the deadline is 2 years and 7 months after promulgation of a new or revised NAAQS. b. If the EPA notifies the state/tribe via **Federal Register** notice, letter or guidance that it intends to complete the initial area designations process according to a schedule other than a 2-year or 3-year timeline, the deadline is 5 months prior to the date specified for final designations decisions in such EPA notification.

[a] Where data years 1, 2, and 3 are those years expected to be considered in state and tribal recommendations.

[b] Where data year 4 is the additional year of data that the EPA may consider when it makes final area designations for the new/revised NAAQS under the standard designations schedule.

[c] Where data year 5 is the additional year of data that the EPA may consider when it makes final area designations for the new/revised NAAQS under an extended designations schedule.

[d] The date by which air agencies must certify their ambient air quality monitoring data in AQS is annually on May 1 of the year following the year of data collection. The EPA cannot require air agencies to certify data prior to this date. In some cases, however, air agencies may choose to certify a prior year's data in advance of May 1 of the following year, particularly if the EPA has indicated its intent to promulgate final designations in the months of May, June, July or August. Exceptional event flagging, initial description, and demonstration deadlines for ''early certified'' data will follow the deadlines for ''year 4'' and ''year 5'' data.

Table 10. Examples by Month of How the Proposed Revised Schedule for Exceptional Event Flagging and Documentation Submission for Data to be Used in Initial Area Designations Would Apply

		Month of NAAQS Promulgation, State and Tribal Recommendation, and Final Designations												
Exceptional Event / Regulatory Action	**Exceptional Event Deadline Schedule[c]**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May[d]**	**Jun[d]**	**Jul[d]**	**Aug[d]**	**Sep**	**Oct**
		Oct 2015	**Nov 2015**	**Dec 2015**	**Jan 2016**	**Feb 2016**	**Mar 2016**	**Apr 2016**	**May 2016**	**Jun 2016**	**Jul 2016**	**Aug 2016**	**Sep 2016**	**Oct 2016**
Exceptional event data flagging and initial description deadline for data years 1, 2, and 3.[a]	If state and tribal recommendations for the new/revised NAAQS are due August through January, then the flagging and initial description deadline will be the July 1 prior to the recommendation deadline. If state and tribal recommendations for the new/revised NAAQS are due Feb through July, then the flagging and initial description deadline will be the January 1 prior to the recommendation deadline.	July 1, 2016 (data years 2013, 2014, 2015)	July 1, 2016 (data years 2013, 2014, 2015)	July 1, 2016 (data years 2013, 2014, 2015)	July 1, 2016 (data years 2013, 2014, 2015)	Jan 1, 2017 (data years 2013, 2014, 2015)	Jan 1, 2017 (data years 2013, 2014, 2015)	Jan 1, 2017 (data years 2013, 2014, 2015)	Jan 1, 2017 (data years 2013, 2014, 2015)	Jan 1, 2017 (data years 2014, 2015, 2016)	Jan 1, 2017 (data years 2014, 2015, 2016)	July 1, 2017 (data years 2014, 2015, 2016)	July 1, 2017 (data years 2014, 2015, 2016)	July 1, 2017 (data years 2014, 2015, 2016)
Exceptional event demonstration submittal deadline for data years 1, 2, and 3.[a]	No later than the date that state and tribal recommendations are due to EPA.	by Oct 2016 (data years 2013, 2014, 2015)	by Nov 2016 (data years 2013, 2014, 2015)	by Dec 2016 (data years 2013, 2014, 2015)	by Jan 2017 (data years 2013, 2014, 2015)	by Feb 2017 (data years 2013, 2014, 2015)	by Mar 2017 (data years 2013, 2014, 2015)	by Apr 2017 (data years 2013, 2014, 2015)	by May 2017 (data years 2013, 2014, 2015)	by June 2017 (data years 2014, 2015, 2016)	by July 2017 (data years 2014, 2015, 2016)	by Aug 2017 (data years 2014, 2015, 2016)	by Sep 2017 (data years 2014, 2015, 2016)	by Oct 2017 (data years 2014, 2015, 2016)
AQS Q&A and data certification	Annually on May 1 of the year following the year of data collection	May 1	May 1	May 1	May 1	May 1	May 1	May 1	May 1	May 1	May 1	May 1	May 1	May 1
Exceptional event data flagging, initial description, and exceptional event demonstration submittal deadline for data year 4[b] and potential data year 5.[c]	By the last day of the month that is 1 year and 7 months after promulgation of a new or revised NAAQS, unless either option a or b applies. a. If the EPA follows a 3 year designation schedule, the deadline is 2 years and 7 months after promulgation of a new or revised NAAQS. b. If the EPA notifies the state/tribe via *Federal Register* notice, letter or guidance that it intends to complete the initial area designations process according to a schedule other than a 2-year or 3-year timeline, the deadline is 5 months prior to the date specified for final designations decisions in such EPA notification.	by May 31, 2017 (data year 2016)	by June 30, 2017 (data year 2016)	by July 31, 2017 (data year 2016)	by Aug 31, 2017 (data year 2016 and potentially 2017)	by Sep 30, 2017 (data year 2016 and potentially 2017)	by Oct 31, 2017 (data year 2016 and potentially 2017)	by Nov 30, 2017 (data year 2016 and potentially 2017)	by Dec 31, 2017 (data year 2016 and potentially 2017)	by Jan 31, 2018 (data year 2017)	by Feb 28/29, 2018 (data year 2017)	by Mar 31, 2018 (data year 2017)	by Apr 30, 2018 (data year 2017)	by May 31, 2018 (data year 2017)
State & Tribal Recommendations to EPA		**Oct 2016**	**Nov 2016**	**Dec 2016**	**Jan 2017**	**Feb 2017**	**Mar 2017**	**Apr 2017**	**May 2017**	**June 2017**	**July 2017**	**Aug 2017**	**Sep 2017**	**Oct 2017**

EPA notifies States/Tribes of intended modifications to recommendations (RAs send 120-day letters)	June 2017	July 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	June 2018
Administrator Promulgates Final Designations	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	June 2018	July 2018	Aug 2018	Sep 2018	Oct 2018

a - Where data years 1, 2, and 3 are those years expected to be considered in state and tribal recommendations.

b - Where data year 4 is the additional year of data that the EPA may consider when it makes final area designations for the new/revised NAAQS.

c - Where data year 5 is the additional year of data that the EPA may consider when it makes final area designations for the new/revised NAAQS under an extended designations schedule.
d -The date by which air agencies must certify their ambient air quality monitoring data in AQS is annually on May 1 of the year following the year of data collection. The EPA cannot require air agencies to certify data prior to this date. In some cases, however, air agencies may choose to certify a prior year's data in advance of May 1 of the following year, particularly if the EPA has indicated its intent to promulgate final designations in the months of May, June, July or August. Exceptional event flagging, initial description, and demonstration deadlines for "early certified" data will follow the deadlines for "year 4" and "year 5" data.

Additionally, in conjunction with proposing exceptional event schedules related to implementing any revised O_3 standards, the EPA is also proposing to remove obsolete regulatory language associated with exceptional event

schedules for historical standards. The EPA expects to propose additional revisions to the Exceptional Events Rule in a future notice and comment rulemaking effort and will solicit public comment on other, non-schedule related, aspects of the Exceptional Events Rule at that time.

VI. Ambient Monitoring Related to Proposed O_3 Standards

A. Background

The EPA is proposing to: Revise the state-by-state O_3 monitoring seasons; revise the PAMS monitoring requirements; revise the FRM for measuring O_3; and revise the FEM testing requirements. The EPA is also proposing to make additional minor changes to the FEM testing requirements for NO_2 and particulate matter in part 53 as discussed below.

The EPA is proposing to extend the length of the required O_3 monitoring season in some states to be appropriate for the O_3 NAAQS revision finalized in 2008, as well as a final revised O_3 standard, if a revision is finalized in 2015.

The EPA is proposing to make changes to the PAMS monitoring requirements in 40 CFR part 58, Appendix D section 5. Section VI.C of this preamble provides background on the current PAMS monitoring requirements, recent efforts to re-evaluate the current PAMS requirements, and a summary of the proposed PAMS requirement revisions.

The EPA is proposing to revise the FRM to establish a new, additional technique for measuring O_3 in the ambient air. This new technique is based on nitric oxide-chemiluminescence (NO–CL) methodology. Because of the similarity of this new chemiluminescence technique to the existing ethylene-chemiluminescence (ET–CL) methodology, the EPA proposes that it be incorporated into the existing O_3 FRM, using the same calibration procedure. Appendix D of 40 CFR part 50 would be revised to include both the original ET–CL as well as the new NO–CL methodology. A minor change is proposed to the existing O_3 FRM calibration procedure, which would be applicable to both of the chemiluminescence FRM methodologies. The proposed change in section 4.5.2.3 of the calibration procedure in appendix D provides for more flexibility in the range of the linearity test.

The only substantial changes proposed to the requirements of 40 CFR part 53 are in Tables B–1 and B–3 of subpart B. Table B–1 has been updated in recent years with regard to FRM and FEM methods for SO_2 (74 FR 64877, December 8, 2009) and CO (76 FR 54294, August 31, 2011) to be more consistent with current analyzer performance capabilities. Similar changes to Table B–1 are proposed here for methods for O_3. Modest changes to Table B–3 would add new interferent test concentrations specifically for NO–CL analyzers, adding a test for NO_2. Also, the table would clarify that the existing test concentrations apply to ET–CL O_3 analyzers.

In addition, the EPA is making minor additional changes to Part 53 including: conforming changes to the FEM testing requirements in Table B–1 and Figure B–5 for NO_2; extending the period of time for the Administrator to take action on a request for modification of a FRM or FEM from 30 days to 90 days; and removing an obsolete provision for manufacturers to submit Product Manufacturing Checklists for certain PM monitors.

B. Revisions to the Length of the Required O_3 Monitoring Seasons

Unlike the ambient monitoring requirements for other criteria pollutants that mandate year-round monitoring, O_3 monitoring is only required during the seasons of the year that are conducive to O_3 formation. These seasons vary in length from place to place as the conditions conducive to the formation of O_3 (*i.e.,* seasonally-dependent factors such as ambient temperature, strength of solar insolation, and length of day) differ by location.[230] In some locations, conditions conducive to O_3 formation are limited to the summer months of the year. For example, in states with colder climates such as Montana and South Dakota, the currently required O_3 monitoring season is four months long. However, in other states with warmer climates such as California, Nevada, and Arizona, the currently required O_3 monitoring season is year-round.[231]

Based on the O_3 NAAQS revision that was finalized in 2008, as well as the proposed NAAQS revisions discussed in this rulemaking, the EPA has determined that lengthening the O_3 monitoring seasons may be appropriate. Ambient O_3 concentrations could approach or exceed the level of the 2008 NAAQS, as well as the proposed NAAQS, more frequently and during more months of the year. The EPA has done an analysis to address the issue of whether extensions of currently required monitoring seasons are appropriate (Rice, 2014). In this analysis, we determined the number of days where one or more monitors had a daily maximum 8-hour O_3 average equal to or above 0.060 ppm in the months outside the currently-required state O_3 monitoring season using data from monitors that collected O_3 data year-round in 2010–2013.[232] We find that this level, taking into consideration reasonable uncertainty, serves as an appropriate indicator of ambient conditions that may be conducive to the formation of O_3 concentrations that approach or exceed the 2008 NAAQS or the proposed 8-hour average range of 0.065 to 0.070 ppm. Although we refer to these days as ''exceedance days'' in the analysis, this 0.060 ppm threshold is simply a conservative benchmark that is below the levels proposed for the revised NAAQS. Proposals for revising each state's required monitoring season are based on the observed ''exceedance days'' where the 8-hour average daily maximum was ≥0.060 ppm in and surrounding the state. The EPA considered a number of factors including out-of-season ''exceedance days'' either before or after the current O_3 monitoring season, the pattern of ''exceedance days'' in the out-of-season months, and regional consistency. We note that seasonal O_3 patterns vary year-to-year due primarily to highly variable meteorological conditions conducive to the formation of early or late season elevated O_3 concentrations in some years and not others. The EPA believes it is important that O_3 monitors operate during all periods when there is a reasonable possibility of ambient levels approaching the level of the proposed NAAQS.

The EPA reviewed the year-round, O_3 data for 2010 through 2013. A year-round monitor was identified as ''year-round'' if it had at least 20 daily observations in all 12 months, for at least 1 year of the 4 year period. During the 2010–2013 data period, all states operated a portion of their monitoring network outside of their required O_3 monitoring season and reported the data to the EPA Air Quality System (AQS).

[230] See 40 CFR part 58 Appendix D, section 4.1, Table D–3 for a table of required O_3 seasons.

[231] Certain states, such as California and Arizona, have approved shorter seasons for a subset of O_3 sites, based on Regional Administrator review and approval (see 40 CFR part 58, Appendix D, section 4.1(i) for the waiver authority).

[232] Approximately 800 O_3 monitors are currently operated year-round, representing greater than 50% of the total O_3 monitoring network of about 1500 monitors. They include monitors that are mandated to operate year-round due to the required O_3 season and other monitors that are voluntarily operated year-round by states and other organizations including EPA-operated monitors at Clean Air Status and Trends Network (CASTNET) sites.

The EPA's analysis found the frequency of observed ''exceedance days'' of daily maximum 8-hour average O_3 readings of ≥0.060 ppm to be quite high in several states across the country in months outside of the currently required monitoring season. A total of 43 states experienced at least one ''exceedance day'' outside of their current O_3 season; 21 states had ''exceedance days'' only before the required monitoring season; 4 states had ''exceedance days'' only after the required monitoring season; and 18 states had ''exceedance days'' both before and after the required monitoring season. In some cases, the frequency of ''exceedance days'' before the current O_3 season was high, with four states (South Dakota, Colorado, Wyoming, and Utah) experiencing between 31 and 230 out-of-season ''exceedance days'' from 2010 to 2013 at monitors operating year-round.

Basing O_3 monitoring season requirements on the goal of ensuring monitoring when ambient O_3 levels approach or exceed the level of the proposed NAAQS supports established monitoring network objectives described in Appendix D of Part 58, including the requirement to provide air pollution data to the general public in a timely manner [233] and to support comparisons of an area's air pollution levels against the NAAQS. The EPA believes that frequency of ''exceedance days'' in which daily maximum of 8-hour O_3 levels are observed to be greater than or equal to a threshold level of 0.060 ppm in months outside the currently required O_3 monitoring season supports the proposed lengthening of the O_3 monitoring season requirements for certain states.

The operation of O_3 monitors during periods of time when ambient levels approach or exceed the level of the proposed NAAQS ensures that persons unusually sensitive to O_3 are alerted to potential levels of health concern allowing them to take precautionary measures. The majority of O_3 monitors in the U.S. report to AIRNOW,[234] as well as to state-operated Web sites and automated phone reporting systems. These programs support many objectives including real-time air quality reporting to the public, O_3 forecasting programs, and the verification of real-time air quality forecast models.

The specific proposed changes to the required state O_3 monitoring seasons are detailed in the proposed changes to Table D–3 of 40 CFR part 58, Appendix D (O_3 Monitoring Season by State). Although 43 states had at least one exceedance day outside the current monitoring season, changes are proposed for only 33 of those states. These proposed changes would entail an increase of 1 month for 23 states (Connecticut, Delaware, District of Columbia, Idaho, Illinois, Iowa, Kansas, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Northern Texas, Virginia, and West Virginia), an increase of one and one half months for Wisconsin, an increase of two months for four states (Indiana, Michigan, Montana, and North Dakota), an increase of four months for Florida and South Dakota, an increase of five months for Colorado, and an increase of seven months for Utah. For Wyoming, we are proposing to add three months at the beginning of the season and remove one month at the end of the season, resulting in a net increase of two months. Ozone season requirements are currently split by Air Quality Control Region (AQCR) in Louisiana and Texas. Included in the state-by-state accounting is the proposal to lengthen the required season in the northern part of Texas (AQCR 022, 210, 211, 212, 215, 217, and 218) by one month. Southern Texas O_3 monitors in AQCRs 106, 153, 213, 214, and 216 would remain on a year-round schedule. In some states with limited available data and few exceedance days outside the current season, proposed changes were made by considering regional consistency and using supporting information from the surrounding states; these changes were all minor, involving the proposed addition of 1 month to the current required season in Iowa, Missouri, and West Virginia.

The EPA solicits comment on the proposed changes to the required O_3 monitoring seasons. We note that EPA Regional Administrators have previously approved certain deviations from the required O_3 monitoring seasons through rulemakings (64 FR 3028, January 20, 1999; 67 FR 57332, September 10, 2002; and 69 FR 52836, August 30, 2004). The current ambient monitoring rule, in paragraph 4.1(i) of 40 CFR part 58 Appendix D (71 FR 61319, October 17, 2006), allows the EPA Regional Administrators to approve changes to the O_3 monitoring season without rulemaking. The EPA is retaining the rule language allowing such deviations from the required O_3 monitoring seasons in the proposed revision to paragraph 4.1(i) of 40 CFR part 58, Appendix D. The proposed changes to O_3 monitoring season requirements, if finalized, will revoke previous Regional Administrator-granted waiver approvals. As appropriate, monitoring agencies could seek new waivers. Post-final rule requests submitted along with relevant supporting information by states for monitoring season waivers from the revised requirements will be reviewed by Regional Administrators using, at a minimum, occurrences of the moderate AQI level, the frequency of out-of-season O_3 NAAQS exceedances, and regional consistency. Any deviations based on the Regional Administrator's waiver of requirements must be described in the state's annual monitoring network plan and updated in the AQS.

Current regulations permit O_3 monitors located at NCore multi-pollutant stations to be counted toward meeting minimum network monitoring requirements. The NCore network requirements were promulgated in the October 17, 2006 (71 FR 61317) revisions to ambient monitoring regulations in order to build a long-term, nationwide network that supports multiple objectives including air quality trends analyses, model evaluation, ecosystem studies, and assessment of transport between urban and rural areas. In the 2006 rulemaking, the EPA did not propose a different O_3 monitoring season for NCore stations.

NCore stations are required to operate a full suite of gaseous and particulate matter monitors as well as basic meteorology to support the objectives. Given the potential value of NCore data to support year-round scientific studies, the EPA believes that it is appropriate to require O_3 monitors at NCore stations to be operated year-round. Accordingly, the EPA proposes that the required monitoring season for NCore stations be January through December regardless of the length of the required O_3 monitoring season for the remainder of the SLAMS (State and Local Air Monitoring Stations) monitors within a state.

The EPA has estimated the cost of the proposed changes to the O_3 seasons. The results are detailed in the EPA ICR #2313.03 and summarized in Section VIII.B., ''Paperwork Reduction Act''. The estimated cost is $1,668,433 which is about 7% of the total average annual cost of $24,115,182 for the national O_3 monitoring network. This estimate is based on the current requirements in 40 CFR part 58 and the proposed requirements in this rule. We note however, that greater than 50% of the monitors are currently operated year-round due to existing requirements, as

[233] Public reporting requirements are detailed in 40 CFR part 58 Appendix G, Uniform Air Quality Index (AQI) and Daily Reporting.

[234] See *http://airnow.gov/*.

well as other monitors that are voluntarily operated year-round by the states. Taking into consideration the number of year-round O_3 monitors that are operated due to existing requirements, as well as on a discretionary basis by states, the incremental cost of these proposed changes is reduced from $1,668,433 to approximately $230,000, which is less than 1% of the total average annual cost of the national O_3 monitoring network.

Considering the timing of this proposal and the final rulemaking (court ordered deadline of October 1, 2015) and associated burden on state/local monitoring agencies, we propose that implementation of the revised O_3 seasons become effective at SLAMS (including NCore sites) on January 1, 2017. The EPA is proposing to add paragraph 58.13 (g) of 40 CFR part 58 to require that monitors operating under the requirements of section 4.1 of 40 CFR part 58, Appendix D operate on the applicable required O_3 monitoring seasons effective January 1, 2017 as listed in Table D–3 of appendix D to this part. We solicit comment on whether the revised seasons could be implemented beginning January 1, 2016 for all monitors or for a subset of monitors, such as those currently operating year-round or on a schedule that corresponds to the proposed O_3 season. If we determine, based on any such comments that implementation could occur earlier in such cases, we could proceed to final action requiring earlier implementation.

C. Revisions to the Photochemical Assessment Monitoring Stations (PAMS)

Section 182 (c)(1) of the CAA required the EPA to promulgate rules for enhanced monitoring of O_3, oxides of nitrogen, and VOCs for nonattainment areas classified as serious (or above) to obtain more comprehensive and representative data on O_3 air pollution. In addition, Section 185B of the CAA required the EPA to work with the National Academy of Sciences (NAS) to conduct a study on the role of O_3 precursors in tropospheric O_3 formation and control. In 1992, the NAS issued the report entitled, ''Rethinking the Ozone Problem in Urban and Regional Air Pollution'', (NAS, 1991).

In response to the CAA requirements and the recommendations of the NAS report, on February 12, 1993 (58 FR 8452), the EPA revised the ambient air quality surveillance regulations to require PAMS in each O_3 nonattainment area classified as serious, severe, or extreme (''PAMS areas'').[235] As noted in EPA's Technical Assistance Document (TAD) for Sampling and Analysis of Ozone Precursors (U.S. EPA, 1998), the objectives of the PAMS program are to: (1) Provide a speciated ambient air database which is both representative and useful in evaluating control strategies and understanding the mechanisms of pollutant transport by ascertaining ambient profiles and distinguishing among various individual VOCs; (2) provide local, current meteorological and ambient data to serve as initial and boundary condition information for photochemical grid models; (3) provide a representative, speciated ambient air database which is characteristic of source emission impacts to be used in analyzing emissions inventory issues and corroborating progress toward attainment; (4) provide ambient data measurements which would allow later preparation of unadjusted and adjusted pollutant trends reports; (5) provide additional measurements of selected criteria pollutants for attainment/nonattainment decisions and to construct NAAQS maintenance plans; and (6) provide additional measurements of selected criteria and non-criteria pollutants to be used for evaluating population exposure to air toxics as well as criteria pollutants.

The original PAMS requirements called for two to five sites per area depending on the area's population. Four types of PAMS sites were identified including upwind (Type 1), maximum precursor emission rate (Type 2), maximum O_3 (Type 3), and extreme downwind (Type 4) sites. Each PAMS site was required to measure O_3, NO, NO_2, speciated VOCs, selected carbonyl compounds, and selected meteorological parameters. In addition, upper air meteorological monitoring was required at one site in each PAMS area.

In the October 17, 2006 monitoring rule (71 FR 61267), the EPA revised the PAMS requirements to only require two PAMS sites per PAMS area.[236] The intent of the revision was to ''allow PAMS monitoring to be more customized to local data needs rather than meeting so many specific requirements common to all subject O_3 nonattainment areas; the PAMS changes would also give states the flexibility to reduce the overall size of their PAMS programs—within limits—and to use the associated resources for other types of monitoring they consider more useful.'' In addition to reducing the number of required sites per PAMS area, the 2006 revisions also limited the requirement for carbonyl measurements (specifically formaldehyde, acetaldehyde, and acetone) to areas classified as serious or above for the 8-hour O_3 standard. This change was made in recognition of carbonyl sampling issues which were believed to cause significant uncertainty in the measured concentrations.

Twenty-two areas were classified as serious or above O_3 nonattainment at the time the PAMS requirements were promulgated in 1993. On July 18, 1997 (62 FR 38856), the EPA revised the averaging time of the O_3 NAAQS from a 1-hour averaging period to an 8-hour averaging period. On June 15, 2005 (70 FR 44470), the EPA revoked the 1-hour standard in most areas of the country; however, PAMS requirements were identified as requirements that had to be retained in the anti-backsliding provisions[237] included in that action. Therefore, PAMS requirements continue to be applicable to areas that were classified as serious or above nonattainment for the 1-hour O_3 standard as of June 15, 2004. Currently, 25 areas are subject to the PAMS requirements with a total of 75 sites. As will be discussed in detail later, the current PAMS sites are concentrated in the North East and California with relatively limited coverage in the rest of the country (Cavender, 2014).

As discussed above, the first PAMS sites began operation in 1994, and have been in operation for over 20 years. Many changes have occurred during that time that have changed the O_3 problem in the U.S. as well as our understanding of it. The O_3 standard has been revised multiple times since the PAMS program was first implemented. On July 18, 1997, the EPA revised the O_3 NAAQS to a level of 0.08 ppm, with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration. On March 28, 2008 (73 FR 16436), the EPA revised the O_3 standard to a level of 0.075 ppm, with a form based on the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration. These changes in the level and form of the O_3 NAAQS, along with notable decreases in O_3 levels in most parts of the U.S., have changed the landscape of the O_3 problem in the U.S. At the time of the first round of designations for the 8-hour standard

[235] Additional information on the O_3 designation process can be obtained at EPA's O_3 designations Web page at *http://www.epa.gov/groundlevelozone/designations/*.

[236] One Type 2 site and either a Type 1 or a Type 3 site are currently required.

[237] Refer to 40 CFR part 51.905

(June 15, 2005), only five areas were classified as serious or above for the 8-hour standard as compared to 22 areas that were classified as serious or above for the 1-hour standard.[238] While the number of serious and above areas decreased, the number of nonattainment areas remained nearly the same. In addition, much of the equipment used at PAMS sites is old and in need of replacement. New technologies have been developed since the inception of the PAMS program that should be considered for use in the network. For these reasons, the EPA determined that it would be appropriate to re-evaluate the PAMS program and associated requirements in light of current O_3 issues.

In 2011 (U.S. EPA, 2011c), the EPA initiated an effort to re-evaluate the PAMS requirements in light of changes in the needs of PAMS data users and the improvements in monitoring technology. The EPA consulted with CASAC's, Air Monitoring and Methods Subcommittee (AMMS) to seek advice on potential revisions to the technical and regulatory aspects of the PAMS program; including changes to required measurements and associated network design requirements. The EPA also requested advice on appropriate technology, sampling frequency, and overall program objectives in the context of the most recently revised O_3 NAAQS and changes to atmospheric chemistry that have occurred over the past 10–15 years in the significantly impacted areas. The CASAC AMMS met on May 16 and May 17, 2011, and provided a report with their advice on the PAMS program on September 28, 2011 (U.S. EPA, 2011c). In addition, the EPA met multiple times with the National Association of Clean Air Agencies (NACAA) Monitoring Steering Committee (MSC) to seek advice on the PAMS program. The MSC includes monitoring experts from various state and local agencies actively engaged in ambient air monitoring and many members of the MSC have direct experience with running PAMS sites. As discussed in more detail in the appropriate sections below, the EPA took into consideration advice from the CASAC AMMS and the MSC in proposing changes to the PAMS requirements.

Based on the findings of the PAMS evaluation and the consultations with the CASAC AMMS and NACAA MSC, the EPA is proposing to revise several aspects of the PAMS monitoring requirements including changes in 1) network design, 2) VOC sampling, 3) carbonyl sampling, 4) nitrogen oxides sampling, and 5) upper air meteorology measurements. The following paragraphs describe the changes being proposed including the rationale for the proposed changes. Timing and other implementation issues associated with these proposed changes are discussed at the end of this section.

1. Network Design

As discussed above, the current PAMS network design calls for two sites (a Type 2, and a Type 1 or Type 3) per PAMS area. In their report (U.S EPA, 2011c), the CASAC AMMS found ''that the existing uniform national network design model for PAMS is outdated and too resource intensive,'' and recommended ''that greater flexibility for network design and implementation of the PAMS program be transferred to state and local monitoring agencies to allow monitoring, research and data analysis to be better tailored to the specific needs of each O_3 problem area.'' While stating that the current PAMS objectives were appropriate, the AMMS report also stated that ''objectives may need to be revised to include both a national and regional focus because national objectives may be different from regional objectives.'' The NACAA MSC also advised the EPA that the existing PAMS requirements were too prescriptive and may hinder state efforts to collect other types of data that were more useful in understanding their local O_3 problems.

The EPA agrees with CASAC that the PAMS objectives include both local and national objectives, and believes that the current PAMS network design is no longer suited for meeting either sets of objectives. As part of the PAMS evaluation, it was determined that at the national level the primary use of the PAMS data has been to evaluate photochemical model performance. Due to the locations of the current PAMS areas and the current network design, existing PAMS sites are clustered along the northeast and west coasts leading to significant redundancy in these areas and very limited coverage throughout the remainder of the country (Cavender, 2014). The resulting uneven spatial coverage greatly limits the value of the PAMS data for evaluation of model performance. CASAC (U.S. EPA, 2011c) noted the spatial coverage issue and advised that EPA should consider requiring PAMS measurements in areas in addition to ''areas classified as serious and above for the O_3 NAAQS to improve spatial coverage.'' The EPA also agrees with CASAC and the NACAA that the PAMS requirements should be revised to provide monitoring agencies greater flexibility in meeting local objectives.

The EPA is proposing changes to the network design requirements that we believe will better serve both national and local objectives. The EPA is proposing a two part network design. The first part of the design includes a network of fixed sites (required PAMS sites) intended to support O_3 model development and the tracking of trends of important O_3 precursor concentrations. The second part of the network design includes monitoring agency directed Enhanced Monitoring Plans which allow monitoring agencies the needed flexibility to implement additional monitoring capabilities to suit the needs of their area.

The EPA considered a number of options to revise the fixed site portion of the network design (Cavender, 2014). An initial option considered was to require all NCore sites to make PAMS measurements regardless of O_3 attainment status. This option would take advantage of the existing NCore infrastructure and would result in a relatively wide geographic distribution of sites. However, it was noted that this option would place some PAMS measurements in areas with relatively low O_3 levels and would also result in a network of approximately 80 required sites, which would strain existing resources with a somewhat larger network than the current situation, and could make it difficult to also implement the desired state-directed Enhanced Monitoring Plans. The second option considered was to require only NCore sites in O_3 nonattainment areas to collect PAMS measurements. This option would provide the benefits discussed above for collecting PAMS measurements at existing NCore sites. This option would also reduce the total number of sites required and focus efforts in areas with higher, non-attaining, levels of O_3. The final option considered would add a population limit in addition to the consideration of O_3 attainment status at NCore sites. An illustration of this example would be a PAMS requirement that applied only to NCore sites in O_3 nonattainment areas with a population greater than a given threshold, for example, Core Based Statistical Areas with 1,000,000 people or more. This approach would continue the current practice of focusing PAMS resources in areas of elevated O_3 readings with an additional consideration that measurements in these larger population areas would be

[238] PAMS requirements continue to apply to all areas classified as serious or above as of June 15, 2005 due to anti-backsliding provisions of 40 CFR 51.905.

sufficient to characterize O_3 formation on a national basis.

After considering the above options as well as the comments of CASAC and NACAA, the EPA believes that an approach focused primarily on the use of the existing NCore sites in O_3 nonattainment areas provides an appropriate balance to the consideration of O_3 levels as well as population, noting that a majority of NCore sites are already located in the larger urban areas of each state. Accordingly, the EPA is proposing to require PAMS measurements at any existing NCore site in an O_3 nonattainment area (either based on the 2008 O_3 NAAQS or the 2015 O_3 NAAQS if finalized) in lieu of the current PAMS network design requirements.[239] The NCore network is a multi-pollutant monitoring network consisting of 80 sites (63 urban, 17 rural) and is intended to support multiple air quality objectives including the development and model evaluation of photochemical models (including both $PM_{2.5}$ and O_3 models), and the tracking of regional precursor trends. NCore sites are sited in typical neighborhood scale locations which are more suitable than source impacted locations for evaluation of grid models typical of current photochemical models and tracking of trends in pre-cursor concentrations. The EPA believes NCore sites are well suited for O_3 model development and evaluation.

The proposal to require PAMS measurements at existing NCore sites in O_3 nonattainment areas would replace the existing PAMS network design.[240] This change would keep roughly the same number of required PAMS sites while improving spatial coverage (Cavender, 2014). Based on the range of the O_3 NAAQS being proposed today and current O_3 design value estimates (based on 2011–2013 air quality data), the number of required sites is estimated to be between 48 and 65, which compares to 50 currently required sites, and 75 currently operating sites. Potential redundancy in the existing network would be reduced while important network coverage in the Southeast and Midwest would be added. The improved spatial coverage will also improve the EPA's ability to track trends in precursor concentrations regionally. The EPA notes that in limited situations, an O_3 nonattainment area may not have an NCore site and in those cases, the area would only be subject to the requirement for an Enhanced Monitoring Plan as discussed in more detail below. The EPA believes that the network coverage provided by existing NCore sites in O_3 nonattainment areas would be adequate for the national PAMS objectives discussed above, and that requiring PAMS sites, in addition to Enhanced Monitoring Plans, in those O_3 nonattainment areas without NCore sites would not substantially improve the network coverage.

The EPA notes that the proposed network design change would provide significant cost efficiencies. By adding PAMS measurements to existing NCore sites, the PAMS network would be taking advantage of existing infrastructure and measurements currently being collected at NCore sites. NCore sites already have the larger, climate-controlled shelters that are necessary to operate the automated gas chromatographs (''auto-GCs'') used to collect speciated VOCs. In addition, existing NCore sites currently collect data on many of the required PAMS measurements including O_3, CO, total reactive nitrogen (NO_y), and meteorological measurements including wind speed and direction, temperature, and relative humidity.

While the EPA believes these proposed changes will result in fixed network cost savings for the overall network on a national basis, individual monitoring agencies may see either an increase or a decrease in burden as a result of these proposed changes. Monitoring agencies in O_3 nonattainment areas who are not currently affected by the existing PAMS requirements would be required to add PAMS measurements to their existing NCore sites, while several monitoring agencies with existing PAMS sites would not be required to continue PAMS monitoring if these proposed requirements are promulgated.[241] As discussed later in this preamble, the EPA is proposing a staggered compliance schedule for the proposed PAMS requirements in recognition of the need for capital investment and staff training at these sites.

The EPA recognizes that in limited situations, existing NCore sites may not be the most appropriate locations for making PAMS measurements. For example, an existing PAMS site in an O_3 nonattainment area may be sited at a different location than the existing NCore site. In this case, it may be appropriate to continue monitoring at the existing PAMS site to support ongoing research and to maintain trends information. To account for these situations, the EPA is also proposing to provide the EPA Regional Administrator the authority to approve an alternative location for a required PAMS sites where appropriate.

The EPA seeks comment on the network design revision proposed above, the requirement for PAMS measurements at NCore sites in O_3 nonattainment areas, and the removal of current multi-site PAMS network design requirements. The EPA also solicits comment on whether, instead of requiring PAMS measurements at all NCore sites in nonattainment areas, we should instead adopt one of the other options discussed above, for example, using both attainment status and population thresholds, that may result in a fixed PAMS monitoring network that is either smaller or larger than what will result from the proposed requirement.

The second part of the proposed PAMS network design includes monitoring agency directed enhanced O_3 monitoring activities intended to provide data needed to understand an area's specific O_3 issues. To implement this part of the PAMS network design, the EPA is proposing to add a requirement for states with O_3 nonattainment areas to develop an ''Enhanced Monitoring Plan.'' These Enhanced Monitoring Plans, which are to be submitted as part of their required Annual Monitoring Network Plan (40 CFR 58.10), would be reviewed and approved by the EPA Regional Administrator as part of the annual plan review process. The purpose of the Enhanced Monitoring Plan is to improve monitoring for ambient concentrations of O_3, NO_X/NO_y, VOCs, and meteorology. The goal of the Enhanced Monitoring Plan is to allow monitoring agencies flexibility in determining and collecting the data they need to understand their O_3 problems, consistent with this purpose and the advice obtained from the CASAC AMMS and the NACAA MSC. Types of activities that might be included in the Enhanced Monitoring Plan include (but are not limited to) additional PAMS

[239] Although enhanced monitoring for O_3, oxides of nitrogen, and VOCs is specifically required for areas classified at least serious for the O_3 NAAQS by section 182(c)(1) of the CAA, the EPA has concluded that requiring enhanced monitoring for all O_3 nonattainment areas is appropriate for the purposes of monitoring ambient air quality and better understanding O_3 pollution.

[240] While the EPA is proposing to replace the multi-site design, monitoring agencies would be encouraged to identify the type of PAMS site the NCore site represents. In most cases, NCore sites would likely be classified as either a Type 2 or Type 3 site. In limited situations, rural NCore sites might be subject to these proposed requirements, in which case, these sites would likely be either Type 1 or Type 4 sites.

[241] Monitoring agencies would be able to seek approval to shut down non-required PAMS sites at their discretion pursuant to the requirements detailed in 40 CFR 58.14.

sites (*e.g.,* upwind or downwind sites), additional O_3 and NO_X monitoring, ozonesondes or other aloft measurements, rural measurements, mobile PAMS sites, additional meteorological measurements, and episodic or intensive studies. The savings from a smaller less costly fixed network of required PAMS sites would be available for re-investment in the development and implementation of the proposed Enhanced Monitoring Plans.

2. Speciated VOC Measurements

Measurement of speciated VOCs important to O_3 formation is a key aspect of the PAMS program. Currently, the existing PAMS requirements allow for a number of options in measuring speciated VOCs at PAMS sites which include 1) hourly measurements using an auto-GC, 2) eight 3-hour samples daily using canisters, or 3) one morning and one afternoon sample with a 3-hour or less averaging time daily using canisters plus continuous total non-methane hydrocarbon (TNMHC) measurements.

The EPA believes that the options provided for VOC measurements limit the comparative value of the data being collected, and is proposing to require instead that all required PAMS sites measure and report hourly speciated VOCs using an auto GC. More complete and consistent speciated VOC data nationally would better help meet certain objectives of the PAMS program described above (*e.g.,* a speciated ambient air database useful in evaluating control strategies, analyzing emissions inventory issues, corroborating progress toward attainment, and evaluating population exposure to air toxics). Furthermore, as noted by the CASAC AMMS, hourly VOC data are ''particularly useful in evaluating air quality models and performing diagnostic emission attribution studies. These data can be provided on a near real-time basis and presented along with other precursor species (*e.g.,* oxides of nitrogen and carbon monoxide) collected over similar averaging times.'' Longer time-averaged data are of significantly lower value for model evaluation.[242] In addition, creating consistent monitoring requirements across the network will provide better data for analyzing regional trends and spatial patterns.

At the time the original PAMS requirements were promulgated, the canister options were included because the EPA recognized that the technologies necessary to measure hourly average speciated VOCs concentrations were relatively new and may not have been suitable for broad network use. At that time, gas chromatographs designed for laboratory use were equipped with auto-samplers designed to ''trap'' the VOC compounds from a gas sample, and then ''purge'' the compounds onto the GC column. The EPA did not believe that auto-GCs were universally appropriate due to the technical skill and effort necessary at that time to properly operate an auto-GC.

While the basic principles of auto-GC technology have not changed, the hardware and software of modern auto-GCs are greatly improved over that available at the time of the original PAMS requirements. Based on advice from the CASAC AMMS, the EPA has initiated an evaluation of current auto-GCs potentially suitable for use in the PAMS network. Based on the preliminary results, the EPA believes that typical NCore site operators, with appropriate training, will have the skill necessary to operate a modern auto-GC successfully. Considering the advances in auto-GC technology, the added value obtained from hourly data, and the proposed move of PAMS measurements to NCore sites in O_3 nonattainment areas, the EPA is proposing to require hourly speciated VOC sampling at all PAMS sites. The EPA notes that this proposed requirement would effectively prevent the use of canisters to collect speciated VOCs at the required PAMS sites. However, canister sampling may continue to be an appropriate method for collecting speciated VOCs at other locations as part of the proposed Enhanced Monitoring Plans.

While the EPA believes that the proposed transition to hourly speciated VOC sampling is the appropriate strategy to take advantage of improved technology and to broaden the utility of collected data, we are also mindful of the additional rigidity that the proposed mandatory use of auto-GCs may have for monitoring agencies, especially those that have experience with and have established effective and reliable canister sampling programs. Therefore, the EPA is requesting comment on the proposed requirement for hourly VOC sampling as well as the range of alternatives that might be appropriate in lieu of a strict requirement. Such alternatives could range from a more formal process where monitoring agencies could request a Regional Administrator-granted waiver from the hourly VOC requirements through the Annual Monitoring Network Plan process to collect canister-based speciated VOC data, to a more flexible set of alternatives where canister sampling could be retained based on each monitoring agency's evaluation of programmatic needs as well as their own logistical and technical capabilities.

3. Carbonyl Sampling

Carbonyls include a number of compounds important to O_3 formation that cannot currently be measured using the auto-GCs or canisters used at PAMS sites to measure speciated VOCs.[243] The current method for measuring carbonyls in the PAMS program is Compendium Method TO–11A (U.S. EPA, 1999). In this method, carbonyl compounds are adsorbed and converted into stable hydrazones using dinitrophenylhydrazine (DNPH) cartridges. These cartridges are then analyzed for the individual carbonyl compounds using liquid chromatography (LC) techniques. Three carbonyls (formaldehyde, acetaldehyde, and acetone) are currently required to be measured in the PAMS program.

In 2006, the EPA revised the PAMS requirements such that carbonyl sampling was only required in areas classified as serious or above nonattainment for O_3 under the 8-hour O_3 standard which effectively reduced the applicability of carbonyl sampling to a few areas in California. This change was made in recognition that there were a number of issues with Method TO–11A that raised concerns with the uncertainty in the carbonyl data being collected. These issues include interferences (humidity and O_3) and breakthrough (*i.e.,* overloading of the DNPH cartridge) at high concentrations. While solutions for these issues have been investigated, these improvements have not been incorporated into Method TO–11A.

A recent evaluation of the importance of VOCs and carbonyls to O_3 formation determined that carbonyls, especially formaldehyde, are very important to O_3 formation (Cavender, 2013). CASAC AMMS (U.S. EPA, 2011c) also noted the importance of carbonyls stating that ''There are many compelling scientific reasons to measure carbonyls. They are a very important part of O_3 chemistry almost everywhere.'' Due to the importance of carbonyls to

[242] Data of longer than a 1-hour average are often not used in model evaluations due to the complexity of trying to accommodate non-hourly averaged data.

[243] Carbonyls compounds including formaldehyde and acetaldehyde are difficult to analyze by GC with Flame Ionization Detectors (FID). Both of these compounds in their free state, do not respond well to FID detectors. GC analysis is difficult due to the chemical composition of these compounds, increased polarity and their inherently low boiling points.

understanding O_3 chemistry, the EPA believes the need for carbonyl data outweighs the concerns over the uncertainty in the data. Therefore, the EPA is proposing to require all required PAMS sites to measure formaldehyde, acetaldehyde, and acetone. In addition, EPA is investigating alternatives to further reduce uncertainties in carbonyl data as described below.

To improve the carbonyl data that would be collected at required PAMS sites (and National Air Toxics Trends Station, or NATTS sites which are also currently measuring carbonyls), the EPA has undertaken an effort to improve carbonyl sampling and analysis methods to reduce the uncertainty in carbonyl data. This effort will lead to improvements to the current Method TO–11A by incorporating solutions to sampling and analysis issues that have been identified since Method TO–11A was finalized in 1999, such as the inclusion of an O_3 scrubber in the sampling system to reduce the interference from oxidants such as O_3. Also as part of this effort, the EPA is investigating alternative cartridge materials that have been identified in the literature as a replacement for DNPH that may have better collection efficiency with fewer interferences.

4. Nitrogen Oxides Sampling

It is well known that NO and NO_2 play important roles in O_3 formation (U.S. EPA, 2011a, Section 3.2.2). Under the current network design, Type 2 PAMS sites are required to measure NO_X (which by definition is the sum of NO and NO_2), and Types 1, 3, and 4 sites are required to measure NO_y which by definition includes NO, NO_2, and other oxidized nitrogen compounds (NO_z). NCore sites are also currently required to measure NO_y but are not required to measure NO_2.

In conventional NO_X analyzers, NO_2 is determined as the difference between the measured NO and NO_X concentrations. However, due to the non-selective reduction of oxidized nitrogen compounds by the molybedenum converter used in conventional NO_X monitors, the NO_2 measurement made by conventional NO_X monitors can be biased high due to the varying presence of NO_z compounds that may be reported as NO_2.[244] The unknown bias from the NO_z compounds is undesirable when attempting to understand O_3 chemistry.

Improvements in reactive nitrogen measurements have been made since the original PAMS requirements were promulgated that allow for improved NO_2 measurements. Selective photolytic converters have been developed that are not significantly biased by NO_z compounds (Ryerson et al., 2000). Monitors using photolytic converters are commercially available and have been approved as FEMs for the measurement of NO_2. In addition, methods that directly read NO_2 have been developed that allow for very accurate readings of NO_2 without some of the issues inherent to the ''difference method'' used in converter based NO_X analyzers. However, these direct reading NO_2 analyzers generally do not provide an NO estimate, and would need to be paired with a converter-based NO_X monitor or NO_y monitor in order to also measure NO.

As discussed above, the EPA is proposing to change the PAMS network design such that PAMS measurements would be required at existing NCore sites in O_3 nonattainment areas. NCore sites currently are required to measure NO and NO_y. NCore sites are not currently required to measure NO_2. Due to the importance of accurate NO_2 data to the understanding of O_3 formation, the EPA is proposing to require NO_2 measurements at required PAMS sites. Since existing NCore sites currently measure NO_y, either a direct reading NO_2 analyzer or a photolytic-converter NO_X analyzer should be used to meet the proposed requirement. The EPA believes conventional NO_X analyzers would not be appropriate for making PAMS measurements due to the uncertainty caused by interferences caused by NO_z compounds.

5. Meteorology Measurements

Monitoring agencies are currently required to collect surface meteorology at all PAMS sites. As noted in EPA's TAD (U.S. EPA, 1998) for the PAMS program, the PAMS requirements do not provide specific surface meteorological parameters to be monitored. As part of the implementation efforts for the original PAMS program, a list of recommended parameters was developed and incorporated into the TAD which includes wind direction, wind speed, temperature, humidity, atmospheric pressure, precipitation, solar radiation, and ultraviolet (UV) radiation. Currently, NCore sites are required to measure the above parameters with the exceptions of atmospheric pressure, precipitation, solar radiation, and UV radiation. In recognition of the importance of these additional measurements for O_3, the EPA is proposing to specify that required PAMS sites are required to collect wind direction, wind speed, temperature, humidity, atmospheric pressure, precipitation, solar radiation, and UV radiation. This proposed revision will provide clarity and consistency to the collection of surface meteorological parameters important to the understanding of O_3 formation. If PAMS measurements are moved to NCore sites in O_3 nonattainment areas, as is being proposed, the net impact of this proposed revision to the surface meteorological requirements for PAMS sites is to add the requirement for the monitoring of atmospheric pressure, precipitation, solar radiation, and UV radiation at affected NCore sites.

The existing PAMS requirements also require the collection of upper air meteorological measurements at one site in each PAMS area. The term ''upper air meteorological'' is not well defined in the existing PAMS requirements. As part of the implementation efforts for the original PAMS program ''mixing height'' was added to the PAMS TAD as a recommended meteorological parameter to be monitored.

Most monitoring agencies installed radar profilers to meet the requirement to collect upper air meteorology. Radar profilers provide data on wind and speed at multiple heights in the atmosphere. Radio acoustic sounding system (RASS) profilers are often included with radar profilers to obtain atmospheric temperature at multiple heights in the atmosphere and to estimate mixing height. The EPA recognizes that the upper air data on wind speed and wind direction from radar profilers can be very useful in O_3 modeling. However, many of the current PAMS radar profilers are old and in need of replacement or expensive maintenance. In addition, the cost to install and operate radar profilers at all NCore sites would be prohibitive. Therefore, the EPA is not proposing to require upper air wind speed and direction as required meteorological parameters to be monitored at PAMS sites. Where monitoring agencies find the radar profiler data valuable, continued operation of existing radar profilers or the installation of new radar profilers would be appropriate to consider as part of the state's Enhanced Monitoring Plan.

As discussed above, mixing height is one upper air meteorological measurement that has historically been measured at PAMS sites. A number of methods can be used to measure mixing height in addition to radar profiler

[244] Nitrogen compounds that would likely be reported (along with NO_2) as NO_2 with a conventional NO_X monitor include peroxyacetyl nitrate (PAN), peroxypropionyl nitrate (PPN), peroxymethacryloyl nitrate (MPAN), and nitric acid (HNO_3), and as well as other nitrogen compounds not listed here.

technology discussed above. Recent developments in ceilometer technology allow for the measurement of mixing height by changes in particulate concentrations at the top of the boundary layer (Eresmaa et al., 2006). Ceilometers provide the potential for continuous mixing height data at a fraction of the cost of radar profilers. Due to the importance of mixing height measurements for O_3 modeling, the EPA is proposing to require monitoring agencies to measure mixing height at PAMS sites. The EPA is aware of a large network of ceilometers operated by the National Oceanic and Atmospheric Administration (NOAA) as part of the Automated Surface Observing System (ASOS). The EPA has been in discussions with NOAA regarding the potential for these systems to provide the needed mixing height data, however, the ASOS ceilometers are not currently equipped to provide mixing height data. Nonetheless, the EPA will continue to work with NOAA to determine if the ASOS ceilometers can be upgraded to meet the need for mixing height data, and is including proposed regulatory language that will allow states a waiver to use nearby mixing height data from ASOS or other sources to meet the requirement to collect mixing height data at required PAMS sites.

6. PAMS Season

Currently, PAMS measurements are required to be taken during the months of June, July, and August. This 3-month period is referred to as the ''PAMS Season''. As part of the PAMS re-evaluation, the EPA considered changes to the PAMS season. The 3-month PAMS season was originally selected to represent the most active period for O_3 formation. However, the EPA notes that in many areas the highest O_3 concentrations are observed outside of the PAMS season.[245] As an example, the highest O_3 concentrations in the Mountain-West often occur during the winter months. Data collected during the current PAMS season would have limited value in understanding winter O_3 episodes.

The CASAC AMMS (U.S. EPA, 2011c) noted in their report to the EPA that ''it would be desirable to extend the PAMS monitoring season beyond the current June, July, August sampling period,'' but that ''the monitoring season should not be mandated and rigid; it should be flexible and adopted and coordinated on a regional airshed basis (*i.e.,* within the same O_3 region).'' The EPA agrees with CASAC on the need for flexibility in determining when PAMS measurements should be taken to meet local monitoring needs but also agrees with CASAC that the flexibility ''should not conflict with national goals for the PAMS program.'' A significant benefit of the standard PAMS season is that it ensures data availability from all PAMS sites for national- or regional-scale modeling efforts.

While the EPA agrees with the potential benefit of extending the availability of PAMS measurements outside of the current season, we also considered the burden of requiring monitoring agencies to operate additional PAMS measurements (*e.g.,* hourly speciated VOC) for periods that in some cases, might be much longer than the current 3-month season, for example, if the PAMS season was extended to match each state's required O_3 monitoring season. Being mindful of the potential burden associated with a lengthening of the PAMS season as well as the potential benefits of the additional data, the EPA is proposing to maintain the current 3-month PAMS monitoring season for required PAMS sites rather than extending the PAMS season to other periods where elevated O_3 may be expected. The EPA believes that the 3-month PAMS season will provide a consistent data set of O_3 and O_3 precursor measurements for addressing the national PAMS objectives. Monitoring agencies are encouraged to consider collecting PAMS measurements in additional periods beyond the required PAMS season as part of the proposed Enhanced Monitoring Plan. The monitoring agencies should consider factors such as the periods of expected O_3 exceedances and regional consistency when determining potential expansion of the specific monitoring periods beyond the required PAMS season.

7. Timing and Other Implementation Issues

The EPA recognizes that the proposed changes to the PAMS requirements will require resources and a reasonable implementation schedule if they are promulgated. The proposed network design changes would require monitoring agencies to start collection of PAMS measurements at many NCore sites that are not currently collecting PAMS measurements. These affected monitoring agencies would need to make capital investments (primarily for the installation of auto-GCs, NO_2 monitors, and ceilometers). Monitoring agencies will also need time to develop the expertise, by training existing staff or otherwise, to successfully collect PAMS measurements. The EPA believes that the current national funding level of the PAMS program is sufficient to support these proposed changes, especially in light of the staggered deployment schedule described below. The current grant guidance includes the maintenance of a PAMS capital equipment reserve that could be used to assist monitoring agencies with the purchase of needed equipment. We also recognize that the proposed revisions would result in a potential shifting of PAMS resources, and we would work with the regional offices, affected states, and monitoring organizations such as the NACAA and the Association of Air Pollution Control Agencies (AAPCA) to facilitate any shifts in funding during the implementation phase of the program.

For these reasons, the EPA is proposing a staggered deployment schedule for the proposed changes to the PAMS requirements (including both the monitoring at required PAMS sites and the Enhanced Monitoring Plans). For areas currently designated as nonattainment for O_3 based on the 2008 NAAQS, the EPA is proposing to require monitoring agencies to incorporate the proposed PAMS requirements into their next annual monitoring network plan following promulgation of these proposed changes (due July 1, 2016, based on current schedules) and to comply with these proposed PAMS requirements by the following PAMS season (June 1, 2017, based on current schedules). For new areas designated as O_3 nonattainment based on the initial round of designations following the promulgation of a revised O_3 standard, the EPA is proposing to require monitoring agencies to incorporate the proposed PAMS requirements into their next annual monitoring network plan following designations (due July 1, 2018, based on current schedules) and to comply with new PAMS requirements by the following PAMS season (June 1, 2019, based on current schedules). Finally, the EPA is proposing that areas designated as O_3 nonattainment following the initial round of designations be allowed 2 years after designation to comply with the proposed PAMS requirements. The EPA believes that the proposed compliance schedule will allow monitoring agencies adequate time to implement the proposed PAMS requirements. The EPA solicits comments on whether the proposed implementation schedule is practicable, or whether additional time would be

[245] The current O_3 monitoring season by state in 40 CFR part 58, appendix D, requires monitoring seasons from 4 to 12 months. As noted in section VI.B. of this preamble, the EPA proposes to lengthen the seasons further for 33 states.

warranted for installation of new PAMS sites, the development of Enhanced Monitoring Plans, or other specific new PAMS requirements.

D. Addition of a New Federal Reference Method (FRM) for O_3

To be used in a determination of compliance with the O_3 NAAQS, O_3 monitoring data must be obtained using either a FRM or a FEM, as defined in 40 CFR parts 50 and 53. Nearly all the monitoring methods for O_3 currently used by state and local monitoring agencies are FEM continuous analyzers utilizing a measurement principle based on quantitative measurement of the absorption of UV light by O_3. This type of O_3 analyzer was introduced into the monitoring networks in the 1980s and has since become the most predominant type of method used because of its all-optoelectronic design and ease of installation and use. The existing O_3 FRM utilizes a measurement principle based on quantitative measurement of the chemiluminescence from the reaction of O_3 with ethylene. Ozone analyzers based on this FRM principle are no longer used for routine O_3 field monitoring and are no longer commercially available. The current list of all approved FRMs and FEMs capable of providing ambient O_3 data for use in NAAQS attainment decisions may be found on the EPA's Web site and in the docket for this action (U.S. EPA, 2014g).

The EPA proposes to revise the FRM to establish a new technique for measuring O_3 in the ambient air. This new technique would be a new type of analyzer based on Nitric Oxide-chemiluminescence (NO-CL) methodology. Because of the similarity of this new chemiluminescence technique to the existing ethylene-chemiluminescence (ET-CL) methodology, the EPA proposes that it be incorporated into the existing O_3 FRM, using the same calibration procedure. Appendix D of 40 CFR part 50 would be revised to include both the original ET-CL as well as the new NO-CL methodology. A minor change is proposed to the existing O_3 FRM calibration procedure, which would be applicable to both chemiluminescence FRM methodologies. The proposed change in section 4.5.2.3 of the calibration procedure in Part 50 provides for more flexibility in the range of the linearity test.

FRMs, as set forth in several appendices to 40 CFR part 50, serve two primary purposes. The first is to provide a specified, definitive methodology for routinely measuring concentrations of various ambient air pollutants for comparison to the NAAQS in Part 50, for quality assurance assessment of monitoring data, and for other air monitoring objectives. The second is to provide a standard of comparison for determining equivalence to the specified reference method of alternative and perhaps more practical pollutant measurement methods (equivalent methods, or FEMs) that can be used in lieu of the FRM for routine monitoring.

Some of the FRMs contained in appendices to Part 50 (such as the original SO_2 FRM and the lead FRM) are manual methods that are completely specified in a step-by-step manner. Others (such as the O_3 FRM) are in the form of a measurement principle along with an associated calibration procedure that must be implemented in a commercially-produced FRM analyzer model. Such FRM-type analyzers must be tested and shown to meet explicit performance and other qualification requirements that are set forth in 40 CFR part 53 (Ambient Air Monitoring Reference and Equivalent Methods). Each analyzer model is then considered to be an FRM only upon specific designation as an FRM by the EPA under the provisions of 40 CFR 53.2 (General requirements for a reference method determination).

As pollutant measurement technology advances and changes, the reference methods in part 50 are assessed by the EPA to determine if improved or more suitable measurement technology is available to better meet current FRM needs as well as potential future FRM requirements. New technology can either be presented to the EPA for evaluation by an FEM applicant under 40 CFR 53.16 (Supersession of reference methods), or (as in this case) the EPA can originate the process as provided in 40 CFR 53.7 (Testing of methods at the initiative of the Administrator).

The current FRM for measuring O_3 in the ambient air was promulgated on April 30, 1971 (36 FR 8186), in conjunction with the EPA's establishment (originally as 42 CFR part 410) of the first national ambient air quality standards for six criteria pollutants (including O_3), as now set forth in 40 CFR part 50. On February 8, 1979 (44 FR 8224), the original O_3 FRM calibration procedure was changed from a wet-chemical standard to a UV photometric calibration procedure. Minor updates to technical references were made on July 18, 1997 (62 FR 38895). This FRM is specified as a measurement principle and calibration procedure in Appendix D of Part 50. The measurement principle of the FRM is based on the quantitative measurement of chemiluminescent light intensity emitted by the chemical reaction of O_3 in an air sample with ethylene gas mixed in a measurement cell. This ET-CL measurement is calibrated by the specified calibration procedure, which is based on photometric assay of O_3 calibration concentrations in a dynamic flowing system, using measurement of the absorption of UV light by the O_3 calibration concentrations at a nominal wavelength of 254 nm.

At the time of the FRM's original promulgation, analyzers based on the ET-CL FRM were widely used for field monitoring of O_3. Laboratory testing prior to, during, and following analyzer development indicated that interferences to which the method was susceptible were few and relatively minor in magnitude. Further, subsequent field experience with the FRM analyzers showed them to be stable, accurate, and reliable. Operation of these FRM analyzers requires a supply of ethylene gas, provided by an attendant high-pressure compressed gas cylinder. Installation of this high-pressure cylinder of flammable and potentially explosive gas proved problematic at many field-monitoring sites due to fire codes or other safety restrictions. Further, the ethylene gas cylinder required periodic replacement—a considerable cost and operational inconvenience.

Following the development of FEM O_3 analyzers based on UV absorption, use of these newer UV FEM analyzers eventually supplanted the ET-CL FRM analyzers because the UV analyzers required no gas supply or other reagents and were much easier to install and operate. Currently, nearly all compliance monitoring in the U.S. is carried out with UV absorption type FEM analyzers (Long, 2014). This transition from ET-CL FRM analyzers to UV absorption analyzers in U.S. (as well as world-wide) monitoring networks has become so extensive that analyzer manufacturers no longer manufacture the ET-CL FRM analyzers. The last new O_3 FRM analyzer was designated by EPA in 1979. As a result, no FRM O_3 analyzers are commercially available to serve as reference standards for testing and designation of new O_3 FEM analyzers, for O_3 compliance monitoring, and for quality assurance of field monitors. FRM units manufactured years ago are becoming increasingly difficult to maintain in operational condition due to aging of components and lack of replacement parts (several of the original FRM analyzer manufacturers no longer exist).

Until the last few years, relatively few measurement techniques have been

successfully implemented in a continuous ambient O_3 analyzer model that has achieved designation by the EPA as either an FRM or FEM (U.S. EPA, 2014g). These include the ET-CL technique, the UV absorption technique and differential optical absorption spectroscopy (DOAS, an open-path method represented by two FEM instrument models from different manufacturers). A relatively new technology is nitric oxide (NO)-O_3 chemiluminescence, which is represented by two FEM instrument models from a single manufacturer. An even newer technology is a ''scrubberless'' UV absorption technique that is represented by a single analyzer model for which FEM designation was recently achieved.

As noted above, the ET-CL technique is technically advantageous as an FRM, but its ethylene supply requirement and the lack of commercially available analyzers severely limit its ability to fulfill the needs for an O_3 FRM. DOAS analyzers are not suitable for some FRM purposes because of their open-path nature.

Commercial availability of conventional UV-absorption O_3 analyzers is excellent, and their widespread use makes the measurement technique desirable for consideration as an FRM. However, the technique is susceptible to potential measurement interference from mercury, some volatile aromatic hydrocarbons, water, and other compounds that sometimes occur in ambient air (Spicer et al., 2010). These interferences are substantially reduced by the use of scrubbers (as discussed below) in UV FEM analyzers, such that the technique can be used extensively for compliance monitoring. Although the interferences are substantially reduced by the use of scrubbers, the potential for interferences prevents the technique from consideration as an FRM.

It is important to make a distinction between use of the UV-absorption measurement technique for assay of O_3 concentrations, as described in the FRM calibration procedure of Part 50, Appendix D, and use of the UV absorption technique for measurement of O_3 in ambient air. For assay of calibration concentrations, the technique is used in a system with clean, zero air (air that must be free of contaminants which would cause a detectable response from the O_3 analyzer) such that potential ambient-air-borne interferences are not an issue. Under these clean-air conditions, the UV assay technique is very accurate and highly reproducible, so much so that the National Institute of Standards and Technology (NIST) utilizes it for its O_3 Standard Reference Photometer.

In contrast, use of the UV-absorption technique to measure O_3 in ambient air is much more difficult because of the need to deal with UV-absorbing (and hence potential interfering) species present in ambient air. Ambient UV O_3 monitors typically suppress interferences by using an ''O_3 scrubber'' that attempts to remove O_3 from ambient air without removing potentially interfering species, to create a zero-O_3 reference air that still contains any potentially interfering species. In a differential measurement process that compares the UV absorption measurement of O_3 in the ambient air sample with that in this zero-O_3 reference air, the net effect of interferences is minimized by cancellation. FEM analyzers using such O_3 scrubbers are able to meet the FEM interference test requirements of 40 CFR part 53 and provide adequate O_3 monitoring data at most typical O_3 monitoring sites.

On October 7, 2011, the EPA designated two NO-CL O_3 analyzers as FEMs (76 FR 62402). These analyzers use a variation of the current FRM measurement principle, based on measurement of the chemiluminescence produced by the chemical reaction of O_3 with NO rather than with ethylene. As explained below, the EPA believes that this variation has performance suitable for an O_3 FRM and offers a substantial implementation advantage over the existing FRM.

The NO-CL measurement technique for O_3 is quite similar to the existing ET-CL FRM technique, in that both are based on the measurement of the intensity of the chemiluminescence resulting from a chemical reaction of a reactant with the O_3 in the ambient air sample. The principle difference is that the reactant is NO rather than ethylene. As a potential variation of the FRM measurement principle, the measurement would be calibrated with the same calibration procedure specified in the FRM.

The performance of NO-CL analyzers has been shown to be very similar to the performance of ET-CL FRM analyzers, providing stable, accurate, highly reproducible measurements of ambient O_3 with minimal potential interferences (U.S. EPA, 2014h). As with ET-CL, some minor interference from variable humidity in ambient air can be minimized with a sample air dryer. The analyzers require a supply of NO gas, typically from a high-pressure compressed gas cylinder. However, unlike ethylene, NO is neither flammable nor explosive, so use of the method in field applications is eased considerably relative to use of ET-CL analyzers. Nitric oxide gas is toxic, but it is possible to use a cylinder of much less toxic, non-combustible nitrous oxide (N_2O) gas with a photolytic N_2O-to-NO converter to supply NO gas for the instrument as needed. There will be no requirement for states to switch to NO-CL analyzers; therefore, UV-absorption FEM analyzers can still be used for routine O_3 monitoring. As noted previously, the EPA has designated two NO-CL FEM analyzers (from the same manufacturer), both of which would qualify for re-designation as FRMs if the NO-CL technique is finalized as an FRM. NO-CL analyzers would then be available for those applications where an FRM analyzer is needed.

Because of the similarity of the NO-CL technique to the existing ET-CL technique, the EPA is proposing to amend the ET-CL FRM by adding the NO-CL technique as a variation to the existing FRM measurement principle specified in Appendix D of Part 50. The specified calibration procedure would be applicable to both FRM ET-CL and NO-CL measurement techniques. Since the existing ET-CL FRM measurement principle remains a technically adequate FRM, and the proposed new NO-CL FRM is technically adequate, it is prudent to retain the existing FRM measurement principle. The designation of all currently designated O_3 FEMs is based on comparison to the ET-CL FRM, so retention of the ET-CL FRM allows those FEM designations to be retained.

Adding the proposed NO-CL measurement technique to the current O_3 FRM would allow at least two commercially available FRM analyzer models (currently FEMs) to be re-designated as FRMs to fulfill FRM analyzer needs. Some older FRM analyzers based on the existing ET-CL measurement principle may still be in operable condition, and there is no technical reason to cancel their designation by withdrawing the original ET-CL FRM technique. Additionally, retaining the existing ET-CL FRM technique allows for the possibility of an instrument manufacturer offering an ET-CL FRM analyzer in the future.

The second of the newly introduced O_3 measurement techniques is known as the scrubberless UV absorption (UV–SL) technique. It utilizes the UV-absorption measurement technique that is widely used in O_3 monitoring networks. The new UV–SL technique specifies removal of O_3 from the sample air for the zero reference by a gas-phase reaction with NO rather than via a conventional chemical scrubber. The NO reacts with

the O_3 much faster than with other potential interfering compounds and is very effective at removing the O_3 without affecting other compounds that may be present in the ambient air sample. The differential UV measurement can effectively eliminate interferences to an insignificant level. Other potential interference arising from changes in water vapor concentration can be minimized with a sample air dryer.

The UV–SL technique appears to have characteristics that are advantageous for meeting the requirements of a new O_3 FRM. Analyzers implementing this technique require a supply of NO (such as a high-pressure gas cylinder). As noted previously in connection with the NO–CL technique, NO is neither flammable nor explosive, so use of the method in field applications is eased considerably relative to use of ET–CL analyzers. Use of N_2O gas, also supplied in compressed gas cylinders but less toxic than NO, is also possible with a photolytic N_2O to NO converter. One commercially available UV–SL analyzer was approved as an FEM on June 18, 2014 (79 FR 34734). The performance of the analyzer, as reported by the manufacturer [246] and some initial field and laboratory studies performed by the EPA (U.S. EPA, 2014h), suggests that the analyzer may meet existing, as well as the proposed, requirements for an O_3 FRM.

The CASAC AMMS provided a peer review of the proposed FRM and changes to the Part 53 requirements on April 3, 2014. The CASAC AMMS recommended that the EPA consider the UV–SL as a FRM. The EPA is independently conducting further laboratory and field tests of the UV–SL analyzer to verify its performance. Although this new UV–SL methodology shows substantial promise for future consideration as a new O_3 FRM, there is currently insufficient documented test and performance information available on the method to propose it as a new FRM at this time. The EPA is continuing to study the method and assess its potential suitability as a new O_3 FRM, and the EPA solicits comment on its potential and suitability as an FRM.

The EPA is not proposing to supersede (replace) the existing O_3 FRM measurement principle under the provisions of 40 CFR 53.16. Rather, for the reasons in the preamble and having conducted the necessary tests, the EPA is proposing, consistent with 40 CFR 53.7, to revise the existing O_3 FRM to widen the scope of its ET–CL measurement principle to include the NO–CL measurement technique as well.

Following promulgation of the proposed revised O_3 FRM measurement principle, any new candidate O_3 FRM analyzers would be required to use either the ET–CL or NO–CL measurement principle, and would also be subject to the O_3 FRM performance requirements proposed in 40 CFR part 53. The FRM calibration procedure specified in Appendix D would apply to both O_3 FRM measurement techniques.

A substantial number of laboratory tests have confirmed the excellent performance of the NO–CL analyzers as well as very close agreement with both ET–CL and UV analyzers in collocated field tests. Therefore, the EPA believes the proposed FRM measurement principle that incorporates the NO–CL methodology is the best approach to improve the availability of FRM analyzers for O_3. No other currently known approach or alternative methodology appears to be more appropriate for a new FRM. Adding the NO–CL technology to the existing O_3 FRM is also endorsed by the EPA's CASAC AMMS. The EPA solicits comment on the proposal to retain the existing O_3 FRM measurement principle and amend it to include the NO–CL variation as well. Comments are also solicited on the nature and adequacy of the proposed revised FRM.

The generic description of the FRM measurement principle for the existing ET-CL FRM in Appendix D would be amended to include the NO–CL variation (see the proposed rule text for Appendix D). As noted previously, the new NO–CL technique would also use the same calibration procedure in Appendix D and would be similarly coupled with the explicit O_3 FRM analyzer performance requirements specified in subpart B of 40 CFR part 53. In addition to the incorporation of the NO–CL methodology, numerous minor clarifications, wording changes, additional details, and a more refined numbering system are being proposed for Appendix D. Accordingly, the entire Appendix D is proposed to be revised as identified in the proposed regulatory text.

Because the new NO–CL technique is proposed to be added to the existing FRM measurement principle, while the existing ET–CL FRM principle would be retained and remain in effect, all existing designated FEM analyzer models will continue their designated status. Thus, this action would cause no negative consequences on monitoring agencies, and no disruption of, or required change to, their O_3 monitoring programs. Comparative testing has been carried out at several field monitoring sites under a variety of ambient conditions, and the results confirm that the proposed new NO–CL FRM measurement technique provides ambient O_3 measurements that compare and correlate excellently with measurements using the existing ET–CL measurement principle, with no significant bias, offset, or discrepancy (U.S. EPA, 2014h).

E. Revisions to the Procedures for Testing Performance Characteristics and Determining Comparability Between Candidate Methods and Reference Methods

The only substantial changes proposed to the requirements of Part 53 are in Tables B–1 and B–3 of Subpart B. Table B–1 has been updated in recent years with regard to FRM and FEM methods for SO_2 (74 FR 64877, December 8, 2009) and CO (76 FR 54294, August 31, 2011). Similar update changes to Table B–1 are proposed here for O_3. Modest changes proposed for Table B–3 would add new interferent test concentrations specifically for NO–CL analyzers, adding a test for NO_2. The table would also clarify that the existing test concentrations apply to ET–CL O_3 analyzers. Figure B–5 is revised to correct a minor inconsistency in the ''Calculations'' column for the two ''Precision'' rows to change ''% URL'' to ''% Standard Deviation.''

Several changes to the performance requirements given in Table B–1 are proposed for O_3. The performance requirements for ''standard range'' instruments would be updated to be more consistent with current O_3 analyzer performance capabilities. The noise requirement limit would be reduced from 0.005 to 0.001 ppm for O_3 analyzers, the lower detectable limit would be reduced from 0.010 to 0.003 ppm, and the maximum interference equivalent limits would be reduced from 0.02 to 0.005 ppm for each potential interfering agent (interferent). The performance limit requirement for the total of all interferents is proposed to be withdrawn for O_3 methods. This withdrawal is appropriate because O_3 analyzer test performance, as reported in recent FEM applications, has shown that the limits established for individual interferents are sufficiently effective to define adequate analyzer performance, and the separate limit for the total of all interferences is unnecessary.

Maximum zero drift for O_3 analyzers would be reduced from 0.02 to 0.004 ppm. The existing limit for span drift at 20% of the upper range limit (URL) is proposed to be withdrawn. Analyzer performance test results have clearly

[246] 2B FEM test data via *http://www.twobtech.com/model_211.htm.*

shown that the existing 80% URL limits are fully adequate and better specify span drift performance and that the 20% URL span drift limits are ineffective and unnecessary. The span drift limit applicable to O_3 analyzers is proposed to be reduced from ±5.0% to ±3.0%. Lag time limits would be reduced from 20 to 2 minutes, and rise and fall time limits would be similarly reduced from 15 to 2 minutes.

For precision, the EPA proposes to change the form of the precision limit specifications (at both 20% and 80% of URL) for O_3 analyzers from ppm to percent (of the URL). This change would make the limits responsive to higher and lower measurement ranges, as appropriate, and is consistent with the same change previously made in the corresponding precision requirements for SO_2 and CO analyzers. Both limits would be set at 2% for O_3 analyzers, which is equivalent to, and, therefore effectively unchanged, from the existing limits of 0.01 ppm (for a URL of 0.5 ppm). Although the changes to Part 53 proposed here are generally restricted to methods for O_3, this change in form for the precision limits is proposed to be extended to methods for NO_2 as well, to simplify Table B–1 and make it consistent for all pollutants covered by the Table. The precision limits that would be applicable to methods for NO_2 are proposed to be changed to 4% and 6% of the URL (for 20% and 80% of the URL, respectively). These values are exactly equivalent to the existing limits of 0.020 ppm and 0.030 ppm, respectively, for the specified URL of 0.5 ppm. Therefore, these precision limits for NO_2 remain effectively unchanged, but specified as a percent rather than an absolute concentration. A new footnote is proposed for Table B–1 to clarify that these revised precision limits are given as ''standard deviation expressed as percent of the URL.'' Therefore, Figure B–5 will be revised to correct a minor inconsistency in the ''Calculation'' column for the two ''Precision'' rows to change the ''% URL'' to ''% Standard Deviation.''

The EPA has reviewed the documented performance of currently designated FRM and FEM methods for O_3 (that are still in commercial production or in service in monitoring networks) and has verified that all would meet the proposed new performance requirements for O_3 methods (Long, 2014). Therefore, adoption of the proposed new performance requirements in Table B–1 would not require the withdrawal or cancelation of the FRM or FEM designation of any such O_3 analyzers.

Finally, to meet a need for analyzers with more sensitive measurement ranges for monitoring in relatively clean areas, new, ''lower range'' performance limit requirements are proposed for O_3 analyzers. These lower range limits are set forth in a new ''lower range'' column in Table B–1 and would be optional. But where a lower measurement range is included in the FRM or FEM designation, these proposed new requirements would provide more stringent performance for analyzers commensurate with greater accuracy for low-level measurements in lower-level concentration ranges.

The EPA believes that these proposed changes in the performance requirements of Tables B–1 and B–3 are appropriate, based on analyzer performance data available from analyzer manuals and recent FRM and FEM applications. The EPA solicits comment as to whether the proposed changes are reasonable, appropriate, beneficial, and achievable without undue burden.

The EPA is proposing minor changes to the general provisions in subpart A of Part 53 to ease the administrative burden associated with processing and reviewing modification requests to existing FRMs and FEMs. This change in 40 CFR 53.14(c) will extend the length of time for the Administrator to take action on a request for modification of a reference or equivalent method from 30 days to 90 days. Section 53.14(c) would read: ''Within 90 calendar days after receiving a report under paragraph (a) of this section, the Administrator will take one or more of the following actions:'' The EPA is also proposing to remove the obsolete provision that manufacturers who offered $PM_{2.5}$ or $PM_{10–2.5}$ samplers or analyzers for sale as part of a FRM or FEM may continue to do so only so long as updates of the Product Manufacturing Checklist are submitted annually. This change is accomplished through the removal of section (i) from 40 CFR 53.9 and Figure E–2 from subpart E of Part 53.

VII. Implementation of Proposed O_3 Standards

The proposed revisions to the primary and secondary O_3 NAAQS discussed in sections II.E and IV.G of this preamble, if finalized, would trigger a process under which states [247] make recommendations to the Administrator regarding area designations, and the EPA promulgates the final area designations. States would also be required to review, modify, and supplement their existing SIPs. The proposed O_3 NAAQS revisions would also affect the transportation conformity and general conformity processes. The revised O_3 NAAQS and the subsequent designations process could affect which preconstruction permitting requirements apply to O_3 in some areas and the nature of those requirements in others.

The EPA has regulations in place addressing the requirements for SIPs and several provisions in these existing rules cover O_3 (40 CFR part 51). States likewise have provisions in their SIPs to address air quality for O_3 and to implement the existing O_3 NAAQS. The EPA has also provided general guidance on the development of SIPs for all pollutants and administration of construction permitting programs, as well as specific guidance on implementing the O_3 NAAQS in some contexts under the CAA and the EPA regulations.

When the EPA proposes to revise a NAAQS for a particular criteria pollutant, it considers the extent to which existing EPA regulations and guidance are sufficient to implement the standard and whether any revisions or updates to those regulation and guidance would be helpful or appropriate in facilitating the implementation of the revised standard by states. The CAA does not require that the EPA promulgate new implementing regulations every time that a NAAQS is revised. Likewise, the CAA does not require the issuance of additional implementing regulations or guidance by the EPA before a revised NAAQS becomes effective. Existing EPA regulations may be sufficient in many cases to enable the EPA and the states to begin the process of implementing a revised NAAQS. However, where the nature of revisions to a NAAQS indicate that additional EPA regulations or guidance (or revisions to existing regulations or guidance) may be helpful to implement unique aspects of the revised standard, the EPA endeavors to provide those regulations and guidance in a timely way to facilitate preparation of SIPs plans. It is important to note, however, that the existing EPA regulations in 40 CFR part 51 applicable to SIPs generally and to particular pollutants continue to apply even without such updates. Accordingly, the discussion below provides the EPA's current thoughts about the extent to which revisions to existing regulations and additional guidance might be helpful or appropriate to aid in the

[247] This and all subsequent references to ''state'' are meant to include state, local, and tribal agencies responsible for the implementation of an O_3 control program.

implementation of a revised O_3 NAAQS, should one be finalized through this rulemaking.

This section provides background information for understanding the possible implications of the proposed NAAQS changes in some areas, and describes the EPA's plans for providing revised rules or additional guidance on some subjects in a timely manner to assist states with their implementation efforts under the requirements of the CAA. This section also describes existing EPA interpretations of CAA requirements and other EPA guidance relevant to implementation of revised O_3 NAAQS. Relevant CAA provisions that provide potential flexibility with regard to meeting implementation timelines are also discussed.

This section contains a discussion of how existing requirements to reduce the impact on O_3 concentrations from the stationary source construction in permit programs under the CAA may be affected by the proposed revisions of the O_3 NAAQS. These are the PSD and Nonattainment New Source Review (NNSR) programs. To facilitate the timely implementation of the PSD requirements, the EPA proposes as part of this rulemaking to add a grandfathering provision to its regulations that would apply to certain PSD permit applications that are pending on the effective date of the revised O_3 NAAQS. If the proposed NAAQS revisions are finalized, this grandfathering provision could be finalized at the same time as the revised NAAQS (see section VII.D of this preamble).

The EPA intends to propose additional regulations and issue additional guidance, as necessary, related to the implementation requirements for any revised O_3 NAAQS resulting from this proposal. The EPA intends to take these actions on a schedule that provides timely assistance to air agencies. Accordingly, in this section, the EPA solicits comment on several issues that the agency anticipates addressing in future guidance or regulatory actions to assist with implementation of the revised O_3 NAAQS. Because these issues are not relevant to the establishment of the NAAQS, and the CAA does not require that the EPA provide implementation rules or guidance for each revised NAAQS, the EPA does not expect to respond, nor is the agency required to respond, to these comments in the final action on this proposal. However the EPA expects these comments will be helpful as future guidance and regulations are developed.

A. NAAQS Implementation Plans

1. Background

As directed by the CAA, reducing pollution to meet national air quality standards always has been a shared task, one involving the federal government, states, tribes and local air quality management agencies. The EPA develops regulations and strategies to reduce pollution on a broad scale, while states and tribes are responsible for implementation planning and any additional emission reduction measures necessary to bring areas into attainment. The agency supports implementation planning with technical resources and guidance, while states and local agencies use their knowledge of local needs and opportunities in designing emission reduction strategies that will work best for their industries and communities.

This partnership has proved effective since the EPA first issued O_3 standards more than three decades ago. For example, 101 areas were designated as nonattainment for the 1-hour O_3 standards issued in 1979. As of the end of 2013, air quality in 98 of those areas meets the 1-hour standards. The EPA strengthened the O_3 standards in 1997, shifting to an 8-hour standard to improve public health protection, particularly for children, the elderly, and other sensitive individuals, against effects such as reduced lung function and respiratory symptoms, hospital and emergency room visits for asthma, and possible irreversible damage to the lungs. The 1997 standards drew significant public attention when they were proposed, with numerous parties voicing concerns about states' ability to comply. However, after close collaboration between the EPA, states, tribes and local governments to reduce O_3-forming pollutants, significant progress has been made. Air quality in 90% of the original 113 areas designated as nonattainment for the 1997 O_3 NAAQS now meets the 1997 standards. The EPA designated 46 areas as nonattainment for the 2008 O_3 NAAQS in 2012. We expect these areas to make similar progress in achieving clean air.

The majority of man-made NO_X and VOC emissions that contribute to O_3 formation in the U.S. come from the following sectors: On-road and nonroad mobile sources, industrial processes (including solvents), consumer and commercial products, and the electric power industry. In 2011, the most recent year for which the National Emissions Inventory (NEI) is available, onroad and nonroad mobile sources accounted for about 60% of annual NO_X emissions; and the electric power industry accounted for about nearly 15%. With respect to VOC, industrial processes (including solvents) accounted for about 57% of manmade VOC emissions; and mobile sources accounted for about 39%. Emissions from natural sources, such as trees, also comprise around 70% of total VOC emissions nationally, with a higher proportion during the O_3 season and in areas with more vegetative cover. *See* section VII.F of this preamble for more detail on background O_3.

Since 2000, the EPA has issued numerous emissions and fuels standards for on-road and nonroad mobile sources, as well as emissions standards for many types of stationary sources. Benefits from new engine standards increase each year as older, more-polluting vehicles and engines are replaced with newer, cleaner models. Benefits from fuel programs generally begin as soon as a new fuel is available. The ongoing emission reductions from federal programs such as these will provide for substantial emissions reductions well into the future, and will complement state and local efforts to attain any revised O_3 NAAQS.

Over the past 15 years, the EPA has established new emissions standards under title II of the CAA, 42 U.S.C. 7521–7574, for numerous classes of automobile, truck, bus, motorcycle, earth mover, aircraft, and locomotive engines, and for the fuels used to power these engines. The EPA also established new standards for the smaller engines used in small watercraft, and lawn and garden equipment. In March 2008, the EPA promulgated new standards for locomotive and for marine diesel engines and in April 2010 the EPA promulgated new standards for Category 3 (C3) engines installed on U.S. ocean-going vessels and to marine diesel fuels produced and distributed in the U.S. In September 2011, the EPA and the National Highway Transportation Safety Administration established greenhouse gas and fuel efficiency standards for new 2014–2018 model year medium and heavy-duty engines and vehicles. In addition to improving fuel efficiency and reducing greenhouse gas emissions this rule reduces emissions of NO_X from the subject vehicles. In March 2014, the EPA promulgated Tier 3 standards for tailpipe and evaporative emissions from passenger cars, light-duty trucks, medium-duty passenger vehicles, and some heavy-duty vehicles. The associated gasoline sulfur standard will enable more stringent vehicle emissions standards and will make existing emissions control systems more effective. Compared to current standards, the VOC and NO_X tailpipe

standards for light-duty vehicles represent approximately an 80% reduction from today's fleet average, and the heavy-duty tailpipe standards represent about a 60% reduction in VOC and NO_X.

The emission reductions from all of these mobile source programs are significant and will continue to be realized throughout the implementation period for any revised O_3 NAAQS. The EPA projects that between 2011 and 2025, onroad and nonroad mobile NO_X will decline by more than 60% and onroad and nonroad mobile VOC will decline by more than 50%.[248]

The reduction of VOC emissions from industrial processes has been achieved either directly or indirectly through implementation of control technology standards, including maximum achievable control technology (MACT), reasonably available control technology (RACT), and best available control technology (BACT) standards; or is anticipated due to proposed or upcoming proposals based on generally available control technology or best available controls under provisions related to consumer and commercial products. These standards have resulted in VOC emission reductions of almost a million tons per year accumulated starting in 1997 from a variety of sources including combustion sources, coating categories, and chemical manufacturing. The EPA also finalized emission standards and fuel requirements for new stationary engines. In the area of consumer and commercial products, the EPA finalized new national VOC emission standards for aerosol coatings in 2008 and will review and revise, as necessary, existing rules for household and institutional consumer products, architectural and industrial maintenance coatings, and automobile refinish coatings. Additionally, in O_3 nonattainment areas, we anticipate reductions of an additional 10,000 tons per year as states adopt rules implementing control techniques recommendations issued in 2008 for four additional categories of consumer and commercial products, such as surface coatings and adhesives used in industrial manufacturing operations. These emission reductions primarily result from solvent controls and typically occur where and when the solvent is used, such as during manufacturing processes.

As noted above, the power industry is responsible for a nearly 15% of NO_X emissions across the U.S. Power industry emission sources include large electric generating units (EGU) and some large industrial boilers and turbines. The EPA's Clean Air Interstate Rule (CAIR), issued on March 10, 2005 (70 FR 25612; May 12, 2005), was designed to permanently reduce power industry emissions of NO_X in the eastern U.S. The first phase of the cap was to begin in 2009, and a lower second phase cap was to begin in 2015. The EPA had projected that by 2015, the CAIR and other programs would reduce NO_X emissions during the O_3 season by about 50% and annual NO_X emissions by about 60% from 2003 levels in the Eastern U.S. However, on July 11, 2008, and December 23, 2008, the U.S. Court of Appeals for the DC Circuit (DC Circuit) issued decisions on petitions for review of the CAIR. In its July 11 opinion, the court found CAIR unlawful and decided to vacate CAIR and its associated Federal implementation plans (FIPs) in their entirety. *State of North Carolina* v. *EPA,* 531 F. 3d 896. On December 23, 2008, however, the court granted EPA's petition for rehearing to the extent that it remanded without vacatur for EPA to conduct further proceedings consistent with the Court's prior opinion. Under this decision, CAIR will remain in place only until replaced by EPA with a rule that is consistent with the Court's July 11 opinion.

The EPA issued the final CSAPR on July 6, 2011 (76 FR 48208; August 8, 2011), to replace CAIR. CSAPR requires states to significantly improve air quality by reducing power plant emissions that contribute to O_3 and/or fine particle pollution in other states. CSAPR requires a total of 28 states to reduce annual SO_2 emissions, annual NO_X emissions and/or O_3 season NO_X emissions to assist downwind states in attaining the 1997 O_3 and fine particle and 2006 $PM_{2.5}$ NAAQS. On December 30, 2011, the D.C. Circuit issued an order staying CSAPR and ordering the EPA to continue implementing CAIR. Subsequently, on August 21, 2012, the D.C. Circuit issued an opinion vacating CSAPR. *EME Homer City Generation LP* v. *EPA,* 696 F. 3d 7. In its decision the Court again instructed the EPA to continue administering CAIR. The U.S. and other parties appealed the D.C. Circuit decision to the U.S. Supreme Court and on April 29, 2014, the U.S. Supreme Court issued an opinion reversing the judgment of the D.C. Circuit, upholding the EPA's interpretation of the CAA ''good neighbor'' provision (CAA section 110 (a)(2)(d)(ii)), and remanding the case back to the D.C. Circuit for further proceedings consistent with the Supreme Court opinion. *EME Homer City Generation LP* v. *EPA,* 134 S. Ct. 1584. On June 26, 2014, the U.S. Government filed a motion with the D.C. Circuit to lift the stay of the CSAPR. The D.C. Circuit has since lifted the stay of the rule. Order, Document #1518738, *EME Homer City Generation, L.P.* v. *EPA,* Case #11–1302 (D.C. Cir. Oct. 23, 2014).

The EPA proposed the Clean Power Plan for existing power plants on June 2, 2014 (79 FR 34830; June 18, 2014). In this action the EPA proposed state-specific rate-based goals for CO_2 emissions from the power sector, as well as guidelines for states to follow in developing plans to achieve the state-specific goals. This rule, as proposed, would continue progress already underway to reduce CO_2 emissions from existing fossil fuel-fired power plants in the U.S. Actions taken to comply with the proposed guidelines would reduce emissions of CO_2 and other air pollutants, including SO_2, NO_X and directly emitted $PM_{2.5}$, from the electric power industry. The EPA estimates that the Clean Power Plan, as proposed, would reduce precursors for both O_3 and particulate matter leading to decreases in the concentrations of those pollutants of approximately 25% in 2030.

It should also be noted, in general, that new EGUs are subject to NO_X limits under New Source Performance Standards (NSPS) under CAA section 111, as well as either PSD or NNSR requirements. The EPA's regulations for commercial, industrial and solid waste incinerators set standards for NO_X and several air toxics for all commercial incinerators, as required under Section 129 of the Act. Air toxics rules for industrial boilers will yield co-benefit NO_X reductions as a result of tune-ups and energy efficiency measures, especially from boilers that burn coal. And several new source performance standards and air toxics standards are expected to make further cuts to NO_X and VOC emissions from new and existing sources of pollution. These include upcoming review and revisions for gas turbines and municipal waste combustors, along with proposed requirements for the petroleum refining industry. The NSPS and air toxics standards that have recently taken effect for stationary engines will also make cuts to NO_X and VOC emissions. The EPA also anticipates reductions in O_3 precursors to result from implementation of the Mercury and Air Toxics Standard rule, as well as from measures to address Regional Haze best

[248] ''Regulatory Impact Analysis for the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone,'' (December 2014) at *http://www.epa.gov/ttnecas1/ria.html.*

available retrofit technology (BART) determinations.

While the EPA uses its regulatory opportunities to reduce NO_X and VOCs, the agency also is pursuing non-regulatory efforts as we strive toward cleaner air. Energy Star, a joint program of the EPA and the U.S. Department of Energy, protects the environment and saves money through energy efficient products and practices. Improving energy efficiency in homes, buildings and industry helps reduce all emissions from the power sector—including NO_X—while reducing compliance costs for electricity providers. As part of its new Advance Program, the EPA is working collaboratively with state, local, and tribal governments that want to take steps to reduce air pollution in O_3 and particulate matter attainment areas. Although these areas are not currently subject to nonattainment planning requirements, Advance Program participants are interested in undertaking their own planning efforts with the goal of keeping their air healthy and creating an improved buffer against future air quality violations. Participating areas are implementing a mix of voluntary and mandatory measures relating to mobile, area, and point sources as well as energy efficiency measures, and they are also pursuing education and awareness programs to improve their communities' understanding of air quality issues.

The EPA recognizes that a number of areas of the country have been working to reduce O_3 precursors for many years and now may need to turn to newer, more innovative approaches for reducing emissions as they develop their implementation plans. These approaches, such as smart growth policies and renewable energy portfolios, hold great promise for improved air quality and health, and the EPA is working with air quality agencies and stakeholders to identify ways to include these types of programs in implementation plans. For example, the EPA developed a roadmap for giving SIP credit to energy efficiency/renewable energy projects.[249] Recognition of innovative programs will allow states and tribes to pursue effective strategies that address some of the more challenging issues affecting air quality, such as land use planning, ever increasing motor vehicle use, and planning for long-term energy needs.

With respect to agricultural sources, the U.S. Department of Agriculture (USDA) has approved conservation systems and activities that reduce agricultural emissions of NO_X and VOC. The EPA recognizes that USDA has been working with the agricultural community to develop site-specific conservation systems and activities to control emissions of O_3 precursors. The EPA will continue to work with USDA on these activities with efforts to identify and/or improve the control efficiencies, prioritize the adoption of these conservation systems and activities, and ensure that appropriate criteria are used for identifying the most effective application of conservation systems and activities.

The EPA will work together with USDA and with states to identify appropriate measures to meet the primary and secondary standards, including site-specific conservation systems and activities. Based on prior experience identifying conservation measures and practices to meet the PM NAAQS requirements, the EPA will use a similar process to identify measures that could meet the O_3 requirements. The EPA anticipates that certain USDA approved conservation systems and activities that reduce agricultural emissions of NO_X and VOC may be able to satisfy the requirements for applicable sources to implement reasonably available control measures for purposes of attaining the primary and secondary O_3 NAAQS.

The agency also is active in work to reduce the international transport of O_3 and other pollutants that can contribute to ''background'' O_3 levels in the U.S. Under the Convention on Long-Range Transboundary Air Pollution (LRTAP) of the United Nations Economic Commission for Europe, the U.S. has been a party to the Protocol to Abate Acidification, Eutrophication, and Ground-level Ozone (known as the Gothenburg Protocol) since 2005. The U.S. is also active in the LRTAP Task Force for Hemispheric Transport of Air Pollution, which in 2010 produced a comprehensive assessment of the intercontinental transport of air pollution (including O_3) in the northern hemisphere.

The U.S. has worked bilaterally with Canada under the US-Canada Air Quality Agreement to adopt an Ozone Annex to address transboundary O_3 impacts. The EPA also continues to work with rapidly growing countries such as China on air quality management activities and the development of analytical tools to help these countries address significant air quality problems, including the emissions of O_3-forming pollutants. This work includes supporting China's efforts to rapidly deploy power plant pollution controls that can achieve NO_X reductions of at least 80 to 90%.

We know that developing the implementation plans that outline the steps a nonattainment area will take to meet an air quality standard requires a significant amount of work on the part of state, tribal or local air agencies. The EPA routinely looks for ways to reduce this workload, including assisting with air quality modeling by providing inputs such as emissions, meteorological and boundary conditions; and sharing national-scale model results that states can leverage in their development of their attainment demonstrations. At the same time, we work with air agencies to provide implementation flexibility to the extent allowed by law.

2. Timing of Rules and Guidance

In public comment periods associated with several recent rulemakings, the EPA received comments from a variety of states and organizations asking for rules and guidance associated with a revised NAAQS to be issued in a timely manner. Although issuance of such rules and guidance is not a part of the NAAQS review process, *National Ass'n of Manufacturers* v. *EPA*, 750 F. 3d 921, 926–27 (D.C. Cir. 2014), toward that end the EPA intends to produce appropriate revisions to necessary implementation rules and provided additional guidance in time frames that would be more useful to states when developing their implementation plans than has been the case with some previous rules and guidance.

Certain requirements under the PSD preconstruction permit review program apply immediately to a revised NAAQS upon the effective date of that NAAQS, unless the EPA has established a grandfathering provision through rulemaking. To ensure a smooth transition to a revised O_3 NAAQS, the EPA is proposing a grandfathering provision similar to the one finalized in the 2012 $PM_{2.5}$ NAAQS Rule. *See* section VII.D of this preamble for more details on the PSD program.

Promulgation of the NAAQS starts a clock for the EPA to designate areas as either attainment or nonattainment. State recommendations for area designations are due to the EPA within 12 months of promulgation of the NAAQS. In an effort to allow states to make more informed recommendations, the EPA intends to issue guidance concerning the designations process within 4 months of promulgation of the NAAQS, or approximately 8 months before state recommendations are due. The EPA has issued designation

[249] ''The Roadmap for Incorporating Energy Efficiency/Renewable Energy Policies and Programs into State and Tribal Implementation Plans,'' (July 2012) at *http://epa.gov/airquality/eere/*.

guidance for several NAAQS in recent years. While generally the EPA considers information related to the same factors in making designation decisions, the guidance is tailored to the particular NAAQS. The EPA anticipates that the guidance for a revised NAAQS resulting from this proposal would be similar to the designation guidance for the 2008 O_3 NAAQS. The EPA generally completes area designations 2 years after promulgation of a NAAQS. *See* section VII.C of this preamble for additional details on designations.

Clean Air Act section 110 requires SIPs to be submitted within 3 years of promulgation of a revised NAAQS. These SIPs are referred to as ''infrastructure SIPs.'' The EPA issued general guidance on submitting infrastructure SIPs on September 13, 2013.[250] It should be noted that this guidance did not address certain state planning and emissions control requirements related to interstate pollution transport. Should this guidance need to be modified for this prospective O_3 NAAQS, the EPA intends to issue that updated guidance no later than 1 year after promulgation of a revised O_3 NAAQS. *See* section VII.B.3 of this preamble for additional information on infrastructure SIPs.

The EPA intends to propose any appropriate rules for assisting with implementing any revised O_3 NAAQS resulting from this proposal within 1 year after a revised NAAQS is established. The rules that EPA is considering, as with implementation of previous NAAQS, would address nonattainment area classification methodologies, SIP due dates, attainment dates, and required implementation programs such as NNSR and conformity. At that same time the EPA intends to address any modifications needed as a result of this revised NAAQS to guidance pertaining to developing nonattainment area emissions inventories and attainment demonstrations, and demonstrating conformity. The EPA anticipates finalizing these items by the time areas are designated nonattainment. Finalizing rules and guidance by this time would provide air agencies with the information to develop any CAA-required SIPs associated with nonattainment designations. In an area designated as nonattainment, new major sources and major modifications at existing sources are required to comply with NNSR requirements including the application of ''lowest achievable emission rate'' (LAER) and emissions offsets at ratios prescribed by the CAA. *See* section VII.B.4 of this preamble for additional information on nonattainment SIPs.

3. Section 110 State Implementation Plans

The CAA section 110 specifies the general requirements for SIPs. Within 3 years after the promulgation of revised NAAQS (or such shorter period as the Administrator may prescribe[251]) each state must adopt and submit ''infrastructure'' SIPs to the EPA to address the requirements of section 110(a)(1) and (2), as applicable. These ''infrastructure SIPs'' establish the basic state programs to implement, maintain, and enforce revised NAAQS and provide assurances of state resources and authorities. States are to develop and maintain an air quality management infrastructure that includes enforceable emission limitations, a permitting program, an ambient monitoring program, an enforcement program, air quality modeling capabilities, and adequate personnel, resources, and legal authority. Section 110(b) of the CAA provides that the EPA may extend the deadline for the ''infrastructure'' SIP submission for a revised secondary standard by up to 18 months beyond the initial 3 years. If both the primary NAAQS and a distinct secondary NAAQS are finalized, the EPA currently believes it would be more efficient for states and the EPA if each affected state submits a single section 110 infrastructure SIP that addresses both standards at the same time (*i.e.,* within 3 years of promulgation of the O_3 NAAQS), because the EPA does not at present discern any need for there to be any significant substantive difference in the infrastructure SIPs for the two standards. However, the EPA also recognizes that states may prefer the flexibility to submit the secondary NAAQS infrastructure SIP at a later date. The EPA solicits comment on these infrastructure SIP submittal timing considerations, and specifically on challenges that would justify needing 18 additional months to complete the submission of an infrastructure SIP for the secondary standard.

It is the responsibility of each state to review its air quality management program's infrastructure SIP provisions in light of each revised NAAQS. Most states have revised and updated their infrastructure SIPs in recent years to address requirements associated with recently revised NAAQS. It may be the case that for a number of infrastructure elements, the state may believe it has adequate state regulations already adopted and approved into the SIP to address a particular requirement with respect to the revised O_3 NAAQS. For such portions of the state's infrastructure SIP submittal, the state may provide a ''certification'' specifying that certain existing provisions in the SIP are adequate. Although the term ''certification'' does not appear in the CAA as a type of infrastructure SIP submittal, the EPA sometimes uses the term in the context of infrastructure SIPs, by policy and convention, to refer to a state's SIP submission. If a state determines that its existing EPA-approved SIP provisions are adequate in light of the revised O_3 NAAQS with respect to a given infrastructure SIP element (or sub-element), then the state may make a ''certification'' that the existing SIP contains provisions that address those requirements of the specific CAA section 110(a)(2) infrastructure elements. In the case of a certification, the submittal does not have to include another copy of the relevant provision (*e.g.,* rule or statute) itself. Rather, the submittal may provide citations to the already SIP-approved state statutes, regulations, or non-regulatory measures, as appropriate, which meet the relevant CAA requirement. Like any other SIP submittal, such certification can be made only after the state has provided reasonable notice and opportunity for public hearing. This ''reasonable notice and opportunity for public hearing'' requirement for infrastructure SIP submittals appears at section 110(a), and it comports with the more general SIP requirement at section 110(l) of the CAA. Under the EPA's regulations at 40 CFR part 51, if a public hearing is held, an infrastructure SIP submittal must include documentation by the state that the public hearing was held in accordance with the EPA's procedural requirements for public hearings. See 40 CFR part 51, Appendix V, paragraph 2.1(g), and 40 CFR 51.102.

4. Nonattainment Area Requirements

Part D of the CAA describes the various program requirements that apply to states with nonattainment areas for different NAAQS. Section 182 (found in subpart 2 of Part D) includes the SIP requirements that govern the O_3 program, and supplements the more general nonattainment area requirements in sections 172 and 173. Under CAA section 182, states generally are required to submit attainment

[250] *See* memorandum from Stephen D. Page to Regional Air Directors, ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)'' September 13, 2013.

[251] While the CAA allows the EPA to set a shorter time for submission of these SIPs, the EPA does not currently intend to do so.

demonstration SIPs within 3 or 4 years of the effective date of area designations by the EPA, depending on the classification of the area. These plans need to show how the nonattainment area will attain the primary O_3 standard ''as expeditiously as practicable,'' but no later than within the relevant time frame from the effective date of designations associated with the classification of the area.

Section 181(a)(1) of the CAA establishes classification categories for areas designated nonattainment for the primary O_3 NAAQS. These categories range from ''Marginal,'' the lowest O_3 classification with the fewest requirements associated with it, to ''Extreme,'' the highest classification with the most required programs. Areas with worse O_3 problems are given more time to attain the NAAQS and more associated emission control requirements. Pursuant to previous O_3 NAAQS reviews, the EPA set the secondary NAAQS equal to the primary NAAQS. Thus, previous implementation programs for O_3 standards did not include a separate classification threshold methodology for the secondary NAAQS. For this NAAQS review, which may result in a secondary standard different in form and level compared to the primary standard, the EPA is considering methodologies for establishing the air-quality based thresholds for assigning the section 181 classifications to areas out of attainment with a secondary O_3 NAAQS. Any such methods would be proposed for comment if the EPA finalizes a distinct secondary NAAQS.

There are two main EPA rulemakings relating to implementation of the 2008 O_3 NAAQS. In May 2012, the EPA issued the final Classifications Rule (77 FR 30160; May 21, 2012). The Classifications Rule detailed the classifications approach, established attainment deadlines and revoked the 1997 O_3 NAAQS for purposes of transportation conformity. In June 2013, the EPA proposed a SIP Requirements Rule (78 FR 34178; June 6, 2013) to provide rules and guidance to states regarding development of SIPs to attain the 2008 O_3 NAAQS. The EPA believes that the overall framework and policy approach of the proposed SIP Requirements Rule for the 2008 O_3 NAAQS provides an effective and appropriate template for the general approach states would follow in planning for attainment of a revised primary O_3 standard. The EPA intends to develop and propose a new SIP Requirements Rule that will address, to the extent necessary, any new implementation requirements that would result from any revised O_3 NAAQS. The EPA intends to propose this implementation rule within 1 year after the revised O_3 NAAQS are promulgated, and finalize the implementation rule by no later than the time the area designations process is finalized (approximately 2 years after promulgation of the O_3 NAAQS).

In general, when developing an attainment plan, the state begins with the evaluation of the air quality improvements the nonattainment area can expect in the future due to ''on the books'' existing federal, state, and local emission reduction measures. The state then must conduct a further assessment of relevant NO_X and VOC emission sources in the nonattainment area, and the additional reasonably available control measures (RACM) and reasonably available control technology (RACT) that can be implemented by these sources, in determining how soon the area can attain the standard. Under section 172(c)(1) of the CAA as interpreted by the EPA, attainment demonstrations must include a RACM analysis showing that no additional reasonably available measures could be adopted and implemented such that the SIP could specify an attainment date that is 1 or more years earlier.

The evaluation of these potential emissions reductions and associated air quality improvement is commonly performed with sophisticated air quality modeling tools. Given that O_3 concentrations are affected both by regionally-transported O_3 and O_3 precursor emissions and emissions of precursors from local sources in the nonattainment area (*e.g.,* industrial sources, EGUs, and on-road mobile sources), the EPA recommends the use of regional grid-based models (such as CMAQ and CAMx) to develop O_3 attainment strategies. Although, as described above, the EPA projects significant improvements in O_3 concentrations regionally resulting from a number of ongoing emission reduction programs already in place (*e.g.,* mobile source engine and fuel standards and regulations for power plants) and from a number of recently promulgated rules such as the Cross State Air Pollution Rule (76 FR 48208; August 8, 2011), the Mercury and Air Toxics Standards rule (77 FR 9304; February 16, 2012) and the Tier 3 rule (79 FR 23414; April 28, 2014) that will result in VOC and NO_X reductions from many geographically dispersed sources, local reductions of direct O_3 precursors can also result in important health benefits.

States must also ensure that a nonattainment area will make ''reasonable further progress'' (RFP) in accordance with subpart 2 of the CAA from the time of the nonattainment designation to its attainment date. The amount of RFP required is based on the classification of the nonattainment area. Under the approach outlined in the proposed SIP Requirements Rule for the 2008 O_3 NAAQS, areas designated nonattainment and classified as Moderate would generally be required to reduce emissions by 15% over the first six years after the effective date of designations. Areas classified higher than Moderate would be required to produce additional emission reductions after this 6-year period for an area that average 3% reductions per year. All RFP and attainment plans must also include contingency measures which would apply without significant delay in the event the area fails to attain by its attainment date or meet RFP milestones.

The EPA expects that the same general approach for determining attainment of the previous 1997 and 2008 8-hour O_3 primary standards by the attainment deadline would be followed for determining attainment with any revised primary O_3 standard. Attainment would be evaluated based on the 3 most recent years of certified, complete, and quality-assured air quality data in the nonattainment area. Areas are able to obtain up to two 1-year attainment date extensions provided under CAA section 181 under certain circumstances. Under previous 8-hour O_3 NAAQS rules, an area whose design value based on the most recent 3 years of data exceeds the standard could receive a 1-year attainment date extension if the air quality concentration for the third year alone does not exceed the level of the standard. Similarly, an area that has received a 1-year extension could receive a second 1-year extension if the average of the area's air quality concentration in the ''extension year'' and the previous year does not exceed the level of the standard.

B. Implementing a Distinct Secondary O_3 NAAQS, if One Is Established

In each of the previous O_3 NAAQS reviews the secondary standard was set equal to the primary standard. As discussed in section IV of this preamble, the EPA is proposing to retain the current averaging time and form of the secondary standard and to revise the level. The EPA is also soliciting comment on the alternative approach of revising the secondary standard to a cumulative, seasonal, concentration-weighted form based on the W126 index.

If the EPA were to establish a distinct secondary standard, there would be

unique implementation issues to consider. These could include issues related to, but not limited to, PSD implementation, nonattainment area classification thresholds, attainment planning, and conformity demonstrations. These issues would be addressed in future implementation rules and guidance, as necessary. The EPA solicits comments on the specific kinds of implementation-related issues (with examples, where possible) that air agencies and affected sources would face if a separate and distinct secondary standard is established.

C. Designation of Areas

After the EPA establishes or revises a NAAQS, the CAA directs the EPA and the states to take steps to ensure that the new or revised NAAQS is met. One of the first steps, known as the initial area designations, involves identifying areas of the country that either do not meet the new or revised NAAQS along with the nearby areas that contribute to the violations.

Section 107(d)(1) of the CAA provides that, ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109, the Governor of each state shall . . . submit to the Administrator a list of all areas (or portions thereof) in the state'' that designates those areas as nonattainment, attainment, or unclassifiable. The EPA must then promulgate the area designations according to a specified process, including procedures to be followed if the EPA intends to modify a recommendation. The CAA defines an area as nonattainment if it is violating the NAAQS or if it is contributing to a violation in a nearby area.

Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas (or portions thereof) . . . as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.'' In certain contexts, with respect to the NAAQS, the term ''promulgation'' has been interpreted by the courts to be signature and widespread dissemination of a final NAAQS rule.[252] By no later than 120 days prior to promulgating area designations, the EPA is required to notify states of any intended modifications to their recommendations that the EPA may deem necessary. States then have an opportunity to demonstrate why any proposed modification is inappropriate. Whether or not a state provides a recommendation, the EPA must timely promulgate the designation that the agency deems appropriate.

While section 107 of the CAA specifically addresses states, the EPA intends to follow the same process for tribes to the extent practicable, pursuant to CAA section 301(d) regarding tribal authority and the Tribal Authority Rule (63 FR 7254, February 12, 1998). To provide clarity and consistency in doing so, the EPA issued a 2011 guidance memorandum on working with tribes during the designation process.[253]

As discussed in sections II and IV of this preamble, the EPA is proposing to revise both the primary and secondary O_3 NAAQS, which currently are identical 8-hour standards that were set at 0.075 ppm in the 2008 NAAQS rule (73 FR 16436; March 27, 2008). If the EPA revises the primary and secondary O_3 NAAQS based on this proposal, the EPA intends to complete designations for both NAAQS following the standard 2-year process discussed above. The EPA is required to sign the final rule for this O_3 NAAQS review no later than October 1, 2015, under a court-ordered deadline. In accordance with section 107(d)(4) of the CAA, state Governors (and tribes, if they choose) should submit their initial designation recommendations for a revised primary and secondary NAAQS no later than 1 year after promulgation of any revised O_3 NAAQS (for example, by October 1, 2016, if the EPA promulgates such NAAQS on October 1, 2015.) If the EPA intends to modify any state recommendation, the EPA would notify the appropriate state Governor (or tribal leader) no later than 120 days prior to making final designation decisions. A state or tribe that believes the modification is inappropriate would then have the opportunity to demonstrate to EPA why it believes its original recommendation (or a revised recommendation) is more appropriate. The EPA would take any additional input into account in making the final designation decisions.

Consistent with previous designations, the EPA intends to use area-specific multi-factor analyses to support area boundary decisions for any revised primary or secondary O_3 standards. Historically, the EPA has evaluated information related to the following factors for designations: air quality data, emissions-related data, meteorology, geography/topography, and jurisdictional boundaries. The EPA solicits comment related to establishing area designation boundaries for the proposed revised primary and secondary NAAQS, including any relevant technical information that should be considered by the EPA and the extent to which different considerations may be relevant to establishing boundaries for a distinct secondary NAAQS. As noted earlier, the EPA intends to issue designation guidance to the states shortly after the promulgation of any revised O_3 NAAQS to provide information on the designation process and to assist states in developing their recommendations. The EPA invites preliminary comment on all aspects of the designation process at this time, which the EPA will consider in developing that guidance.

D. Prevention of Significant Deterioration and Nonattainment New Source Review Programs for the Proposed Revised Primary and Secondary O_3 NAAQS

The CAA, at parts C and D of title I, contains NSR requirements that constitute preconstruction review and permitting programs applicable to new major stationary sources and major modifications of existing major sources. The preconstruction review of each new major source and major modification generally applies on a pollutant-specific basis, and the requirements that apply for each pollutant generally depend on whether the area is designated as attainment (or unclassifiable) or nonattainment for that pollutant. For the O_3 NAAQS, in areas designated attainment and unclassifiable, the PSD requirements under part C apply. In nonattainment areas for O_3, the NNSR requirements under part D apply. Collectively, those two sets of permit requirements are commonly referred to as the ''major NSR programs.''

Until areas are designated for the proposed revised O_3 NAAQS, the NSR provisions applicable under an area's designation for the 2008 NAAQS (including any applicable anti-backsliding requirements) would continue to apply. *See* 40 CFR 51.166(i)(2) and 52.21(i)(2). When the

[252] *American Petroleum Institute* v. *Costle,* 609 F.2d 20 (D.C. Cir. 1979).

[253] Page, S. (2011). Guidance to Regions for Working with Tribes during the National Ambient Air Quality Standards (NAAQS) Designations Process, Memorandum from Stephen D. Page, Director, EPA Office of Air Quality Planning and Standards to Regional Air Directors, Regions I–X, December 20, 2011. Available: *http://www.epa.gov/ttn/oarpg/t1/memoranda/20120117naaqsguidance.pdf.*

new designations for any revised O_3 NAAQS are effective, they generally will serve to determine whether the PSD or nonattainment NSR program applies.

1. Prevention of Significant Deterioration (PSD)

The statutory requirements for a PSD permit program set forth under part C (sections 160 through 169 of the CAA) are addressed by the EPA's PSD regulations found at 40 CFR 51.166 (minimum requirements for an approvable SIP) and 40 CFR 52.21 (federal PSD permit program for areas lacking an EPA-approved PSD program in the applicable SIP and for lands owned by the federal government and tribal lands). Both sets of regulations already apply to O_3. *See* 40 CFR 51.166(b)(23), (49); 40 CFR 52.21(b)(23), (50).. Among other things, in attainment and unclassifiable areas, the PSD program requires a new major stationary source or a major modification to an existing major source to apply BACT for each applicable pollutant and to conduct an air quality impact analysis to demonstrate that the proposed source or project will not cause or contribute to a violation of any NAAQS or PSD increment (*see* CAA section 165(a)(3)–(4), 40 CFR 51.166(j)–(k), 40 CFR 52.21(j)–(k)). PSD requirements may also include, in appropriate cases, an analysis of potential adverse impacts on Class I areas (*see* CAA sections 162 and 165).[254] These existing requirements of the PSD program will remain applicable to O_3 and the demonstration required under 40 CFR 51.166(k) and 52.21(k) will apply to any revised O_3 NAAQS when such NAAQS become effective, except to the extent that a pending permit application is subject to a grandfathering provision that the EPA establishes through rulemaking.

To address ambient O_3 impacts of VOC and NO_X precursor emissions from individual stationary sources, Appendix W to 40 CFR part 51 currently directs states to consult with the applicable EPA Regional Office to determine the appropriate techniques on a case-by-case basis, which may or may not involve the use of air quality models, for evaluating whether a PSD source causes or contributes to a violation of the O_3 NAAQS (40 CFR part 51, Appendix W, section 5.2.1.c). At present, the EPA is evaluating the models and techniques available to address atmospheric chemistry of O_3 formation in assessing such single source impacts, and as part of that evaluation has conducted discussions of such tools with the regulatory modeling community. Consistent with its commitment to engage in a rulemaking process to determine whether updates to Appendix W in 40 CFR part 51 are warranted,[255] the EPA is planning to propose a rulemaking in the spring of 2015 to consider whether to update Appendix W. If the EPA concludes that it is technically and scientifically appropriate, it will propose appropriate regulatory updates to Appendix W as part of that rulemaking and may also make related updates to technical guidance, as appropriate. In the meantime, in order to demonstrate that a proposed source or modification does not cause or contribute to a violation of the applicable O_3 NAAQS, PSD permit applicants would follow the current provisions in Appendix W until any revisions to them are in effect.

For PSD, a ''major stationary source'' is one with the potential to emit 250 tons per year (TPY) or more of any regulated NSR pollutant, unless the new or modified source is classified under a list of 28 source categories contained in the statutory definition of ''major emitting facility'' in section 169(1) of the CAA. For those 28 source categories, a ''major stationary source'' is one with the potential to emit 100 TPY or more of any regulated NSR pollutant. A ''major modification'' is a physical change or a change in the method of operation of an existing major stationary source that results first, in a significant emissions increase of a regulated NSR pollutant at a project, and second, in a significant net emissions increase of that pollutant at the source.[256] *See* 40 CFR 51.166(b)(2)(i), 40 CFR 52.21(b)(2)(i).

The EPA's regulations define the term ''regulated NSR pollutant'' to include ''[a]ny pollutant for which a [NAAQS] has been promulgated and any pollutant identified [in EPA regulations] as a constituent or precursor to such pollutant'' (40 CFR 51.166(b)(49); 40 CFR 52.21(b)(50)). These regulations identify VOC and NO_X as precursors to O_3 in all attainment and unclassifiable areas (40 CFR 51.166(b)(49)(i)(a); 40 CFR 52.21(b)(50)(i)(a)). Thus, for O_3, the PSD program currently requires the review and control of emissions of VOC and NO_X, as applicable, as precursors of O_3.

As noted above, section 165(a)(3) of the CAA and the implementing PSD regulations require the owner or operator of a proposed facility to, among other things, demonstrate that ''emissions from construction or operation of such facility will not cause, or contribute to, air pollution in excess of any . . . national ambient air quality standard in any air control region.'' *See also* 40 CFR 51.166(k), 40 CFR 52.21(k). The EPA has interpreted this requirement to include any NAAQS that is in effect as of the date a permit is issued, unless it has grandfathered permit applications from the requirement to demonstrate that the proposed facility does not cause or contribute to a violation of the new or revised NAAQS.[257] *See, e.g.,* 73 FR 28321, 28324, 28340 (May 16, 2008); 78 FR 3253 (Jan. 15, 2013); Memorandum from Stephen D. Page, Director, Office of Air Quality Planning & Standards, ''Applicability of the Federal Prevention of Significant Deterioration Permit Requirements to New and Revised National Ambient Air Quality Standards'' (April 1, 2010). Consistent with this interpretation, any revised O_3 NAAQS finalized through this rulemaking will need to be addressed by PSD permit applicants and permitting authorities, in permits issued on or after the date when the revised NAAQS become effective, unless the permit application has been grandfathered through rulemaking, as described below in this proposal.

Because the complex chemistry of O_3 formation poses significant challenges

[254] Congress established certain Class I areas in section 162(a) of the CAA, including international parks, national wilderness areas, and national parks that meet certain criteria. Such Class I areas, known as mandatory federal Class I areas, are afforded special protection under the CAA. In addition, states and tribal governments may establish Class I areas within their own political jurisdictions to provide similar special air quality protection.

[255] *See* Letter from Gina McCarthy, Assistant Administrator, to Robert Ukeiley, at 1 (Jan. 4, 2012), available at *http://www.epa.gov/scram001/10thmodconf/review_material/Sierra_Club_Petition_OAR-11-002-1093.pdf.*

[256] As explained in 40 CFR 52.21(a)(2)(iv)(a) and 51.166(a)(7)(iv)(a), ''[t]he project is not a major modification if it does not cause a significant emissions increase. If the project causes a significant emissions increase, then the project is a major modification only if it also results in a significant net emissions increase.'' The PSD regulations at 40 CFR 51.166(a)(7) and 52.21(a)(2) also explain in more detail the two-pronged test for determining whether a proposed project at a facility is a major modification.

[257] In the past the EPA has asserted the discretion to take such grandfathering action, under appropriate circumstances, either by rulemaking or through a case-by-case determination for a specific permit application. The United States Court of Appeals for the Ninth Circuit recently vacated a decision by the EPA to issue an individual PSD permit grandfathering a permit applicant from certain requirements. *See Sierra Club* v. *EPA,* 762 F.3d 971 (9th Cir. 2014). In light of that decision, the EPA is no longer asserting authority to grandfather permit applications on a case-by-case basis. However, in the same opinion the court also stated that it did ''not doubt, or express any opinion on, the EPA's traditional authority to employ formal rulemaking to implement grandfathering'' and distinguished that authority from the permit-specific grandfathering at issue in the case before it. *Id.,* at 982, n. 7 & 982–983. Thus, the EPA does not interpret this opinion to limit its authority to grandfather through rulemaking, but rather believes that the decision offers support for such authority.

for the assessing the impacts of individual stationary sources on O_3 formation, the EPA's judgment has been that it was not technically sound to designate a specific air quality model that must be used in the PSD permitting process to make this demonstration for O_3.[258] The EPA has explained that sources must make the demonstration required under CAA section 165(a)(3) and the implementing regulations, that this demonstration necessarily involves an analysis, and has established a process to determine on a case-by-case basis, in consultation with the appropriate EPA Regional Office, what analytical techniques should be used to assess the impact of an individual source [259] (40 CFR part 51, Appendix W, Section 5.2.1.c). The EPA has, however, granted a petition from Sierra Club requesting, among other things, that it initiate rulemaking to designate air quality models for O_3, and consistent with that petition grant, has been going through a process to evaluate potential updates to Appendix W.[260] While that process is underway, individual sources should continue to follow the existing procedures to determine what method is appropriate to use to evaluate their impacts on O_3 formation.

The PSD rules in 40 CFR 51.166(i)(2) and 52.21(i)(2) contain an exemption for particular pollutants from the PSD requirements if the owner or operator of the source demonstrates that the area in which the facility is located is designated as nonattainment for that pollutant under CAA section 107. Thus, new major sources and modifications will generally be subject to the PSD program requirements for O_3 if they are locating in an area that does not have a current nonattainment designation under CAA section 107 for O_3. As explained in the recent proposal for the implementation rule for the 2008 O_3 NAAQS, references to historical nonattainment designations for a revoked standard should not be viewed as current ''nonattainment designation[s] under CAA section 107'' within the meaning of 40 CFR 51.166(i)(2) and 52.21(i)(2) and, therefore, do not trigger the exemption from PSD requirements that would otherwise result from those provisions (78 FR 34216, June 6, 2013).

[258] Letter from Gina McCarthy, Assistant Administrator, to Robert Ukeiley, at 2 (Jan. 4, 2012), available at *http://www.epa.gov/scram001/10thmodconf/review_material/Sierra_Club_Petition_OAR-11-002-1093.pdf.*

[259] *See, e.g., id.*

[260] *See id.* at 1 and 3.

a. PSD Grandfathering Provision

Recognizing that some PSD applications may have already been submitted and could be in the review process when a revised O_3 NAAQS becomes effective, the EPA is proposing a transition plan that would enable certain PSD applications to make the demonstration that the proposed project will not cause or contribute to a violation of any NAAQS with respect to the O_3 NAAQS that were in effect on the date the reviewing authority determines the permit application complete or the date the public notice on the draft permit or preliminary determination is first published (depending on which grandfathering provision applies), rather than the revised O_3 NAAQS.[261]

The EPA is proposing and taking comment on adding a grandfathering provision to EPA's regulations at 40 CFR 51.166 and 52.21 that would apply specifically to two categories of PSD permit applications that are pending when the EPA issues the revised O_3 NAAQS: (1) Applications for which the reviewing authority has formally determined that the application is complete on or before the signature date of the revised NAAQS; and (2) applications for which the reviewing authority has first published a public notice of a draft permit or preliminary determination before the effective date of the revised NAAQS. These two categories are proposed because some states do not do completeness determinations as part of their permit process.

As explained above, the EPA interprets the CAA and implementing PSD regulations at 40 CFR 52.21(k)(1) and 51.166(k)(1) to require that PSD permit applications must include a demonstration that new major sources and major modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued. Thus, if the EPA revises the O_3 NAAQS, any proposed new source or modification with a PSD permit application pending at the time the revised O_3 NAAQS takes effect would be expected to conduct an analysis to demonstrate that it does not cause or contribute to a violation of that NAAQS, absent some type of transition provision exempting the application from that requirement. This demonstration, as noted above, should be completed in consultation with the applicable EPA Regional Office.

Nevertheless, the agency has previously recognized that the CAA provides discretion for the EPA to grandfather PSD permit applications from requirements that become applicable while the applications are pending (45 FR 52683, August 7, 1980; 52 FR 24672, July 1, 1987; 78 FR 3086, January 15, 2013). As discussed in more detail in these referenced actions, section 165(a)(3) of the CAA requires that a permit applicant demonstrate that its proposed project will not cause or contribute to a violation of any NAAQS. At the same time, section 165(c) of the CAA requires that a PSD permit be granted or denied within 1 year after the permitting authority determines the application for such permit to be complete. In addition, section 301 of the CAA authorizes the Administrator ''to prescribe such regulations as are necessary to carry out his functions under this chapter.'' When read in combination, these three provisions of the CAA provide the EPA with the discretion to issue regulations to grandfather pending permit applications from having to address a revised NAAQS where necessary to achieve both CAA objectives to protect the NAAQS and to avoid delays in processing PSD permit applications. Moreover, in a recent opinion the U.S. Court of Appeals for the Ninth Circuit recognized the EPA's traditional exercise of grandfathering authority through rulemaking and indicated that this approach was consistent with statutory requirement to ''enforce whatever regulations are in effect at the time the agency makes a final decision'' because it involved identifying ''an operative date, incident to setting the new substantive standard, and the grandfathering of pending permit applications was explicitly built into the new regulations.'' *Sierra Club* v. *EPA*, 762 F.3d 971, 983 (9th Cir. 2014).

In the EPA's most recent adoption of a grandfathering provision for PSD, it adopted a provision for $PM_{2.5}$ that provides a reasonable transition for implementing certain new PSD requirements related to the 2012 $PM_{2.5}$ NAAQS for pending permit applications that have met certain criteria. As finalized, the $PM_{2.5}$ grandfathering provision included the same two categories of permit applications that

[261] The proposed grandfathering provision is intended to apply to pending PSD permit applications that meet one or both of the specified criteria and that are for sources locating in areas where PSD continues to apply with respect to O_3 at the time the permit is issued. The proposed grandfathering provision is not intended to apply to sources locating in areas where NNSR applies at the time of permit issuance (for example, if the area had been designated as attainment for O_3 when the permit application was submitted but was subsequently designated as nonattainment for O_3 and that nonattainment designation would be in effect when the permit would be issued). For such sources, the permit application must be resubmitted in accordance with the applicable NNSR requirements.

today are being proposed for O_3. *See* 40 CFR 51.166(i)(10) and 52.21(i)(11). In the rulemaking, adding the grandfathering provision for the $PM_{2.5}$ NAAQS, the EPA also provided a detailed rationale and legal basis for including the grandfathering provision in the PSD program. *See* 78 FR 3087 at 3253–59 (January 15, 2013); *see also* 77 FR 39023–24 (June 29, 2012).

When the $PM_{2.5}$ NAAQS grandfathering provision was originally proposed, the EPA provided for only one category of pending PSD applications—applications for which the reviewing authority has published a public notice on the draft permit prior to the effective date of the revised $PM_{2.5}$ NAAQS. A majority of the commenters supported the adoption of a grandfathering provision but some responded that a grandfathering milestone based on the submittal of a complete application would be more appropriate in order to avoid significant burdens associated with having to withdraw an application. These commenters pointed out the significant level of effort, resources and time involved in preparing all of the information necessary for a complete permit application. They claimed that it would be unfair to establish grandfathering milestones beyond the complete application date because the processes and timeframe involved in generating the draft permit or preliminary determination materials and publishing the public notice are largely out of the control of the permit applicant and vary from agency to agency.

Based on this and other pertinent information provided by the commenters, the EPA concluded in that rulemaking that it should add an additional grandfathering milestone to avoid substantial additional burden and delay for permit applications that have reached a stage in the review process by which significant resources have been expended to complete PSD analyses and demonstrations that would have to be redone to address the revised NAAQS. Accordingly, the EPA adopted a grandfathering provision for the $PM_{2.5}$ NAAQS in the final rule that included two milestones for establishing grandfathering eligibility. The EPA believes that these considerations and this rationale also apply to pending PSD permit applications that would be affected by a revised O_3 NAAQS. Accordingly, the EPA is proposing to apply these same two milestones in this proposed rulemaking for the revised O_3 NAAQS.

The proposed grandfathering provision does not apply to any applicable PSD requirements related to O_3 other than the requirement to demonstrate that the proposed source does not cause or contribute to a violation of any revised O_3 NAAQS. Sources with projects qualifying under the grandfathering provision will be required to apply BACT to all applicable pollutants, demonstrate that the project emissions will not cause or contribute to a violation of the existing O_3 NAAQS, and address any Class I area and additional O_3-related impacts in accordance with the PSD regulatory requirements.

For the reasons provided both herein and in the prior EPA actions referenced above, the EPA proposes to amend the federal PSD permitting regulations at 40 CFR 52.21 to add the described grandfathering provision for the proposed O_3 NAAQS revision. Specifically, the proposed provision provides that qualifying new sources and modifications seeking PSD permits under 40 CFR 52.21 shall not be required to demonstrate that their proposed emissions will not cause or contribute to a violation of the revised O_3 NAAQS, but instead must demonstrate that their proposed emissions will not cause or contribute to a violation of the O_3 NAAQS in effect on the date the reviewing authority determines the permit application complete or the date the public notice on the draft permit or preliminary determination is first published, depending on which prong of the grandfathering provision is applicable for that source. *See* proposed 40 CFR 52.21(i)(12).

For sources subject to the PSD program under section 52.21, it should be noted that the EPA intends for a source that satisfies either milestone in the proposed revisions to section 52.21(i) to be grandfathered from this requirement if those revisions are finalized. Accordingly, if a particular source does not qualify under the first milestone based on a complete application, it may qualify under the second milestone based on the issuance of a public notice. Conversely, a source may qualify for grandfathering under the first milestone, even if it does not satisfy the second. As explained below, states with EPA-approved PSD programs in their SIPs would have additional flexibility for implementing the proposed grandfathering provision to the extent that any alternative approach is at least as stringent as the federal provision.

The EPA also proposes that states that issue PSD permits under a SIP-approved PSD permit program should have discretion to ''grandfather'' pending PSD permits in the same manner under these same circumstances. Therefore, the EPA is proposing to revise its rules at 40 CFR 51.166 to provide a comparable exemption applicable to SIP-approved PSD programs, although such states are under no obligation to grandfather. *See* proposed 40 CFR 51.166(i)(11). The EPA recognizes that such states interested in grandfathering PSD sources for O_3 will not have time to revise their rules and submit them to the EPA for approval into the SIP, since the need to grandfather sources will occur immediately upon the effective date of the revised O_3 NAAQS. As explained in an earlier rulemaking, the EPA believes that states implementing a SIP-approved PSD program have the discretion to allow grandfathering consistent with the grandfathering provision contained in the federal rule provisions, even in the absence of an express grandfathering provision in their state rules, if the particular state's laws and regulations may be interpreted to provide such discretion. *See* 78 FR 3086 at 3258.

Because state SIPs cannot be less stringent than federal requirements, the states' discretion must be limited to applying grandfathering consistent with the federal rule provisions for O_3. However, we believe that such consistent application affords states with ample flexibility for implementing the provision. Accordingly, a state may elect to apply both milestones or it may elect to rely solely upon one of the milestones for grandfathering PSD permits for O_3. For example, in states that do not issue a formal completeness determination, the complete application milestone would not serve any practical purpose for grandfathering a PSD source, so the state may choose not to use this milestone. These states may elect to rely solely upon the public notice milestone, regardless of whether it issues formal completeness determinations. However, the EPA anticipates that once a decision is made concerning either the use of both milestones or only one, states will apply the provision consistently to all PSD permit applications that would qualify under the elected milestone(s).

The EPA seeks comments on all aspects of the proposed grandfathering provisions under either 40 CFR 52.21 or 51.166 as they would apply to exempt certain pending PSD permit applications from having to address the revised O_3 NAAQS.

b. PSD Screening Tools

The EPA has historically allowed the use of screening tools to help facilitate the implementation of the NSR program

by reducing the source's burden and streamlining the permitting process for circumstances where pollutant emissions or ambient impacts could be considered *de minimis.* For example, the EPA has established significant emission rates or SERs that are used to determine when the NSR requirements should be applied to a particular new or modified source with regard to each regulated NSR pollutant. *See* 40 CFR 51.166(b)(23) and 52.21(b)(23). For O_3, the EPA established a separate SER in these regulations of 40 tpy for emissions of each O_3 precursor—VOC and NO_X. For PSD, these SER values for VOC and NO_X are used to determine when the proposed major source or major modification must complete PSD review for that precursor, including complying with BACT for that precursor and completing the appropriate air quality analyses associated with the proposed emissions increase of that precursor.

Another key screening tool commonly used for PSD is the significant impact level (SIL). This particular tool is used to determine the extent to which an ambient impact analysis must be completed for the applicable pollutant. The EPA has not established a SIL for O_3. The PSD regulations currently state that ''[n]o *de minimis* air quality level is provided for ozone. However, any net emissions increase of 100 tons per year or more of [VOC] or [NO_X] subject to PSD would be required to perform an ambient impact analysis, including the gathering of ambient air quality data.'' [262] The EPA intends to consider whether it is appropriate to make any revisions to the PSD regulations related to the screening tools for O_3 in a separate rulemaking that will specifically address various implementation issues for O_3. However, there are no such revisions being proposed in today's rulemaking. Until any rulemaking to amend existing regulations is completed, permitting decisions should continue to be based on the existing 40 TPY SER for O_3 precursors (NO_X and VOC) in existing regulations. Further decisions regarding the need for an analysis to assess the impact of an individual source on the O_3 NAAQS and the method of analysis depend on the nature of the source and its emissions, and, as noted above, should be determined in consultation with the EPA Regional Office on a case-by-case basis in accordance with section 5.2.1.c. of Appendix W to 40 CFR part 51.

c. Other PSD Transition Issues

As explained earlier in this section, the EPA anticipates that the existing O_3 air quality in some areas will no longer be in attainment of the primary O_3 standard when it is revised, and that these areas will be designated as ''nonattainment'' at a later date consistent with the designation process set forth for O_3 under the CAA. However, until such nonattainment designation occurs, proposed new major sources or major modifications located in any area designated attainment or unclassifiable for the 2008 O_3 NAAQS will continue to be required to obtain a PSD permit.[263] This raises the question as to how a source can be issued a PSD permit in light of known existing ambient violations of the revised NAAQS.

Section 165(a)(3)(B) of the CAA requires that a proposed source may not construct unless it demonstrates that it will not cause or contribute to a violation of any NAAQS. This statutory requirement is implemented through a provision contained in the PSD regulations at 40 CFR 51.166(k) and 52.21(k). If a source cannot make this demonstration or if its initial air quality impact analysis shows that the source's impact does cause or contribute to a violation, a PSD permit may not be issued until that adverse impact is mitigated.[264] The PSD regulations, however, do not explicitly specify remedial actions that a prospective source can take to address such a situation. Nevertheless, the EPA has historically recognized in regulations and through other actions that sources applying for PSD permits may utilize offsets as part of the required PSD demonstration under the CAA section 165(a)(3)(B), even though the PSD provisions of the Act do not expressly reference offsets, in contrast to the NNSR provisions of the Act.[265]

The EPA has looked to the procedures contained in a separate set of regulations at 40 CFR 51.165(b) to guide the process by which a source that is located in an area designated as attainment or unclassifiable for a NAAQS, but that is determined to cause or contribute to a violation of that NAAQS in any area, can use offsets to mitigate its adverse impact on the NAAQS and ultimately meet the PSD demonstration requirement under CAA section 165(a)(3)(B) and the implementing regulations.[266]

Section 51.165(b) states that plans shall include a preconstruction review permit program (or its equivalent) to satisfy the requirements of CAA section 110(a)(2)(D)(i) for major sources and major modifications, and that the program shall apply to any major stationary source or major modification locating in an area designated attainment or unclassifiable for any NAAQS, when that source would cause or contribute to a NAAQS violation.[267] Paragraph (b)(3) of that regulation provides that the required permit program may include a provision allowing a proposed major source or major modification to reduce the impact of its emissions on air quality by obtaining sufficient emissions reductions to, at a minimum, compensate for its adverse ambient impact where the source or modification would otherwise cause or contribute to a violation of any NAAQS. Although section 51.165(b) refers explicitly to CAA section 110(a)(2)(D)(i), which now addresses transport issues, but not CAA section 165(a)(3)(B), the EPA has previously explained that 51.165(b) may also be interpreted to apply to the section 165(a)(3)(B) demonstration

[262] This language is contained in a footnote in the PSD regulations at 40 CFR 51.166(i)(5)(i) and 52.21(i)(5)(i), and it has not been revisited by the EPA since the issuance of the 8-hour O_3 NAAQS. These values do not reflect a categorical conclusion by the EPA that sources emitting less than 100 tpy of VOCs or NO_X will not cause or contribute to a violation of the current (or any revised) O_3 NAAQS, nor does it reflect a conclusion that such sources should be categorically excluded from the requirement for an ambient impact analysis. Instead, the EPA recommends consultation with the appropriate EPA Regional Office in accordance with section 5.2.1.c of Appendix W when a review of an application for a new source or modification involves emissions less than 100 tpy of either O_3 precursor. *See* Letter from Gina McCarthy, Assistant Administrator, to Robert Ukeiley, at 4 (Jan. 4, 2012), available at *http://www.epa.gov/scram001/10thmodconf/review_material/Sierra_Club_Petition_OAR-11-002-1093.pdf.*

[263] Any proposed major stationary source or major modification for O_3 that does not receive its PSD permit by the effective date of a new nonattainment designation for the area where the source would locate would then be required to satisfy all of the applicable NNSR preconstruction permit requirements for O_3.

[264] See, *e.g.,* Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Division Directors, ''Guidance Concerning Implementation of the 1-hour SO_2 NAAQS for the Prevention of Significant Deterioration Program,'' (August 23, 2010); 44 FR 3278 (January 16, 1979).

[265] See, *e.g., In re Interpower of New York, Inc.,* 5 E.A.D. 130, 141 (EAB 1994) (describing an EPA Region 2 PSD permit that relied in part on offsets to demonstrate the source would not cause or contribute to a violation of the NAAQS). 52 FR 24698 (July 1, 1987); 78 FR 3261–62 (Jan. 15, 2013).

[266] 78 FR 3261 (January 15, 2013); Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Division Directors, ''Guidance Concerning Implementation of the 1-hour SO_2 NAAQS for the Prevention of Significant Deterioration Program,'' (August 23, 2010).

[267] The definition of ''major stationary source'' and ''major modification'' in this regulation is based on the respective definitions in the NNSR regulations at 40 CFR 51.165(a), which are more inclusive than the respective PSD definitions, but clearly include major sources covered by the PSD requirements.

based on the regulatory history (78 FR 3262, n. 256).[268]

Generally, the offset needed to compensate for a proposed source's adverse impact would be determined by the ability of any particular emissions reduction to mitigate the source's adverse impact at the location of the violation. As long as the emissions reduction or offset can be shown to compensate for the source's adverse impact, there is no implied requirement that the amount of the emissions reduction be equal to or greater than the proposed emissions increase. *See* 44 FR 3278 (January 16, 1979). (''Although full emissions offsets are not required, such a source must obtain emissions offsets sufficient to compensate for it air quality impact where the violation occurs.'')

In previous discussions of the use of emissions offsets to help make the demonstration required under CAA section 165(a)(3)(B), the EPA has explained that any emissions used for PSD purposes must meet applicability criteria that are at least as stringent as the offset criteria set forth in the NNSR requirements for offsets under 40 CFR 51.165(a)(3). *See* 78 FR 3262. The EPA continues to believe that these criteria provide the most appropriate criteria for determining the creditability of PSD offsets.

d. PSD for a Distinct Secondary Standard, if One Is Established

As noted above, the CAA requires that proposed new major stationary sources and major modifications demonstrate that their emissions increases will not cause or contribute to a violation of any NAAQS, which includes the primary and secondary NAAQS. For O_3, the existing primary and secondary NAAQS are defined in the same form and at the same level. As described earlier in this preamble, the Administrator is proposing to retain the current averaging time and form and revise the level of the current secondary standard to within the range of 70 to 65 ppb. In addition, among other things, the agency is seeking comment on the alternative approach of revising the secondary standard to establish a distinct O_3 secondary standard. If the agency were to finalize a secondary standard that differs from the primary standard, PSD permit applicants would be required to provide an analysis that specifically addresses the revised secondary standard and make the necessary showing of compliance with that standard, as well as any revised primary standard. Moreover, if such a secondary standard is expressed in a distinctly different form than the primary standard, the required analysis for making the compliance demonstration would need to be consistent with that form.

Should the Administrator decide to establish a distinct secondary NAAQS for O_3, the EPA would consider whether the approaches put forth in any regulatory updates to Appendix W and associated guidance, as noted in this preamble above, are sufficient for making the necessary compliance demonstration for that standard for purposes of PSD. If appropriate, the EPA may consider establishing a surrogacy policy that would allow a source to make the PSD-required demonstration of compliance with a distinct secondary O_3 NAAQS solely through a demonstration of compliance with the primary NAAQS. Therefore, the EPA expects that projects subject to the revised O_3 NAAQS could generally move forward consistent with the PSD program requirements and NNSR program requirements as subject to the revised primary and secondary O_3 NAAQS. The EPA seeks comment on this potential approach as well as any other options that should be considered for showing compliance with any revised primary and secondary O_3 NAAQS.

2. Nonattainment New Source Review

Part D of title I of the CAA includes preconstruction review and permitting requirements for new major stationary sources and major modifications when they locate in areas designated nonattainment for a particular pollutant. As explained in section VII.D.1 of this preamble, the relevant part D requirements are typically referred to as the NNSR program. The EPA's regulations for the NNSR programs are contained in 40 CFR 51.165, 52.24 and Part 51, Appendix S. For example, the EPA has developed minimum program requirements for an NNSR program that is approvable in a SIP, and those requirements, which include requirements for O_3, are contained in 40 CFR 51.165. In addition, 40 CFR part 51, Appendix S contains requirements constituting an interim NNSR program. This program governs NNSR permitting in nonattainment areas that lack a SIP-approved NNSR permitting program, and applies during the time between the date of the relevant designation and the date that the EPA approves into the SIP a NNSR program.[269] This program is commonly known as the Emissions Offset Interpretative Rule, and is applicable to O_3 as well.[270]

As with PSD, the NNSR requirements apply on a pollutant-specific basis. However, in nonattainment areas, NNSR applies only to nonattainment pollutants, that is, pollutants for which an area is designated nonattainment on the date when the permit is issued. As explained in section VII.D.1 of this preamble, prior to the designation of areas for any revised O_3 NAAQS, applicability of either PSD or NNSR for O_3 to a proposed major new or modified source will depend on an area's current designations with regard to the O_3 NAAQS. Accordingly, a major stationary source or major modification proposing to locate in an area currently designated nonattainment for the 2008 O_3 NAAQS must satisfy the NNSR permit requirements for O_3. The EPA is not proposing any new or revised NNSR requirements in this proposal. As explained in section VII.A.2 of this preamble, the CAA requires that area designations for new or revised NAAQS be addressed subsequent to the effective date of such new or revised NAAQS. The EPA anticipates that the area designation process for any revised O_3 NAAQS will be completed within 2 years after the revised NAAQS become effective. Accordingly, any revisions to the existing NNSR requirements for O_3 will be proposed at a later date consistent with the designation process for any revised O_3 NAAQS. The EPA will also at the same time propose any necessary revisions to the NNSR requirements under Appendix S so that states will be able to issue NNSR permits for the revised O_3 NAAQS on and after the effective date of

[268] Briefly, in 1980, the EPA had determined that the statutory requirements under CAA section 165(a)(3)(B), taken together with the requirements of CAA section 110(a)(2)(D) required all major sources locating outside a nonattainment area, but causing or contributing to a NAAQS violation to reduce the impact on air quality so as to assure attainment and maintenance of the NAAQS. 45 FR 31310 (May 13, 1980). In a footnote, the EPA further indicated that this offset requirement must apply to sources causing or contributing to a newly discovered NAAQS violation until the area is designated nonattainment. *See* 45 FR 31310 (May 13, 1980). In the 1980 rule, the EPA adopted section 51.18(k), which was later renumbered section 51.165(b). The EPA revised 51.165(b) to expressly authorize an offset program to meet the requirements of CAA section 110(a)(2)(D)(i), but this provision may also be interpreted to apply to section 165(a)(3)(B), consistent with the EPA's reading of section 51.18(k) in 1980. It is also worth noting that at the time of these rules, before the 1990 CAA amendments, section 110(a)(2)(D) required each state to have ''a permit or equivalent program for any major emitting facility . . . to assure (i) that national air quality standards are achieved and maintained . . ..''

[269] *See* Appendix S, Part I; 40 CFR 52.24(k).

[270] As appropriate, certain NNSR requirements under 40 CFR 51.165 or Appendix S can also apply to sources and modifications located in areas that are designated attainment or unclassifiable in the Ozone Transport Region. *See, e.g.,* CAA 184(b)(2), 40 CFR 52.24(k).

designations of new nonattainment areas for O_3 until such time that their own NNSR program is approved as part of their SIP, where the state does not already have an approved NNSR program applicable to O_3.

This section provides an explanation of some of the key requirements of the NNSR program as it currently applies to O_3. For NNSR, ''major stationary source'' is generally defined as a source with the potential to emit at least 100 tpy of the pollutant for which the area is designated nonattainment. In some cases, however, the CAA and the NNSR regulations define ''major stationary source'' for NNSR in terms of a lower rate dependent on the pollutant. For O_3, in addition to the general threshold level of 100 tpy, lower major source thresholds have been defined for O_3 nonattainment areas based on the stringency of the area's classification. The NNSR program requires the review and control of emissions of both VOC and NO_X as precursors of O_3, and both are reviewed separately in accordance with the applicable major source threshold. For example, the threshold for O_3 nonattainment areas classified as Serious is 50 tpy for both VOC and NO_X. *See* 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*i*) and (a)(1)(iv)(A)(*2*)(*iv*), respectively.

As explained earlier in section VII.D.1 of this preamble, a major modification is a physical change or change in the method of operation of an existing major stationary source that results in both a significant emissions increase, and a significant net emissions increase. To determine whether an emissions increase is significant, the NNSR rules define significant emissions rates or SERs for each applicable pollutant. The SER for VOC is 40 tpy, as is the SER for NO_X. *See* 40 CFR 51.165(a)(1)(x)(A). It should be noted that there are additional more stringent criteria that must be considered in determining a major modification in nonattainment areas classified as Serious, Severe or Extreme for O_3. *See* 40 CFR 51.165(a)(1)(x)(B), (C) and (E).

New major stationary sources and major modifications for O_3 must comply with the LAER as defined in the CAA and NNSR rules, as well as performing other analyses as required under section 173 of the CAA. In addition, appropriate emissions reductions, known as emissions offsets, must be secured to offset the proposed emissions increase of the precursors that trigger NNSR for O_3. The appropriate emissions offset needed for a particular source will depend upon the classification for the O_3 nonattainment area in which the source or modification will locate. Generally, the ratio of the total emissions reduction to the emissions increase is at least 1:1; however, more stringent ratios apply to O_3 nonattainment areas according to the area classification. *See, e.g.,* 40 CFR 51.165(a)(9) and 40 CFR part 51, Appendix S, IV.G.2.

E. Transportation and General Conformity Programs

1. What are transportation and general conformity?

Conformity is required under CAA section 176(c) to ensure that federal actions are consistent with (''conform to'') the purpose of the SIP. Conformity to the purpose of the SIP means that federal activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Conformity applies to areas that are designated nonattainment, and those nonattainment areas redesignated to attainment with a CAA section 175A maintenance plan after 1990 (''maintenance areas'').

The EPA's Transportation Conformity Rule (40 CFR 51.390 and Part 93, subpart A) establishes the criteria and procedures for determining whether transportation activities conform to the SIP. These activities include adopting, funding or approving transportation plans, transportation improvement programs (TIPs) and federally supported highway and transit projects. For further information on conformity rulemakings, policy guidance and outreach materials, *see* the EPA's Web site at *http://www.epa.gov/otaq/stateresources/transconf/index.htm*. The EPA may issue future transportation conformity guidance as needed to implement a revised O_3 NAAQS.

With regard to general conformity, the EPA first promulgated general conformity regulations in November 1993. (40 CFR part 51, subpart W, 40 CFR part 93, subpart B) Subsequently the EPA finalized revisions to the general conformity regulations on April 5, 2010. (75 FR 17254–17279). Besides ensuring that federal actions not covered by the transportation conformity rule will not interfere with the SIP, the general conformity program also fosters communications between federal agencies and state/local air quality agencies, provides for public notification of and access to federal agency conformity determinations and allows for air quality review of individual federal actions. More information on the general conformity program is available at *http://www.epa.gov/air/genconform/*.

2. Why is the EPA discussing transportation and general conformity in this proposed rulemaking?

The EPA is discussing transportation and general conformity in this proposed O_3 NAAQS rulemaking in order to provide affected parties with information on when and how conformity must be implemented after nonattainment areas are designated for a revised O_3 NAAQS. The information presented here is consistent with existing conformity regulations and statutory provisions that are not addressed by this O_3 NAAQS rulemaking. Affected parties would include state and local transportation and air quality agencies, metropolitan planning organizations (MPOs), and federal agencies including the U.S. Department of Transportation (DOT), the U.S. Department of Defense, the U.S. Department of Interior, and the U.S. Department of Agriculture.

3. When would transportation and general conformity apply to areas designated nonattainment for a revised O_3 NAAQS, if one is established?

Transportation and general conformity apply one year after the effective date of nonattainment designations for a revised O_3 NAAQS. This is because CAA section 176(c)(6) provides a 1-year grace period from the effective date of initial designations for any revised NAAQS before transportation and general conformity apply in areas newly designated nonattainment for a specific pollutant and NAAQS.

4. Will transportation and general conformity apply to a distinct secondary O_3 NAAQS, if one is established?

Section 176(c)(1)(A) of the CAA states that conformity to a SIP means ''conformity to an implementation plan's purpose of eliminating or reducing the severity and number of violations of the national ambient air quality standards and achieving expeditious attainment of such standards . . .'' In other words, because the CAA refers to the NAAQS without distinguishing between them, conformity applies to both the primary and secondary NAAQS for all criteria pollutants. Therefore, if a distinct secondary O_3 NAAQS is established, both transportation and general conformity will apply in any areas designated nonattainment for such a NAAQS.

Current transportation and general conformity regulations already apply to such a secondary NAAQS, and nothing in this proposal affects those

transportation and general conformity requirements. The EPA will consider the need to issue additional guidance concerning the implementation of transportation and general conformity in areas designated nonattainment for a distinct secondary O_3 NAAQS, if one is established.

5. What impact would the implementation of a revised O_3 NAAQS have on a state's transportation and/or general conformity SIP?

If the EPA revises the O_3 NAAQS, but does not make specific changes to its transportation or general conformity regulations, then states should not need to revise their transportation and/or general conformity SIPs. The EPA is not proposing any changes to its transportation or general conformity regulations. While we are not proposing any revisions to the general conformity regulations at this time, we recommend, when areas develop SIPs for a revised O_3 NAAQS, that state and local air quality agencies work with federal agencies with large facilities that are subject to the general conformity regulations to establish an emissions budget for those facilities in order to facilitate future conformity determinations under the conformity regulations. Such a budget could be used by federal agencies in determining conformity or identifying mitigation measures if the budget level is included and identified in the SIP. However, because some federal agencies may not have an established facility-wide emissions budget in the SIP for the purpose of meeting general conformity requirements, state, local and tribal agencies are encouraged to maintain ozone SIP emissions inventories on an annual basis, at a minimum, to facilitate compliance of federal agencies with CAA section 176(c). Finally, states with new nonattainment areas may also need to revise conformity SIPs in order to ensure the state regulations apply in any newly designated areas if the existing SIP does include current conformity provisions.

If this is the first time that transportation conformity will apply in a state, such a state is required by the statute and EPA regulations to submit a SIP revision that addresses three specific transportation conformity requirements that address consultation procedures and written commitments to control or mitigation measures associated with conformity determinations for transportation plans, TIPs or projects. (40 CFR 51.390) Additional information and guidance can be found in the EPA's ''Guidance for Developing Transportation Conformity State Implementation Plans'' (*http://www.epa.gov/otaq/stateresources/transconf/policy/420b09001.pdf*).

F. How Background O_3 Is Addressed in CAA Implementation Provisions

1. Introduction

The EPA and state, local and tribal air agencies, need to determine how to most effectively and efficiently use the CAA's various provisions to provide required public health and welfare protection from the harmful effects of O_3. In most cases, reducing man-made emissions of NO_X and VOCs will reduce O_3 formation and provide additional health and welfare protection. The EPA recognizes, however, that ''background'' O_3 levels, which can be significant in some areas on some days, may present a challenge to air agencies in preparing clean air plans. That is, O_3 and O_3-forming pollution from natural and international sources could prevent ambient levels from reaching attainment levels in locations where the impacts of such sources are large relative to the impact of controllable man-made sources of NO_X and VOC emissions within the U.S., especially in locations with few remaining untapped opportunities for local emission reductions.

Climate change may also influence future O_3 concentrations. Modeling studies in EPA's Interim Assessment (U.S. EPA, 2009b) and cited in support of the 2009 Endangerment Finding (74 FR 66,496; Dec. 15, 2009) show that, while the impact is not uniform, simulated climate change causes increases in summertime O_3 concentrations over substantial regions of the country, with increases tending to occur during higher peak pollution episodes in the summer. Increases in temperature are expected to be the principal factor in driving any O_3 increases, although increases in stagnation frequency may also contribute (Jacob and Winner, 2009). These temperature increases could lead to more prevalent wildfires, the impacts of which may lessened by various mitigation measures including taking steps to minimize fuel loading in areas vulnerable to fire.

The term ''background'' O_3 is often used to refer to O_3 that originates from natural sources of O_3 (*e.g.,* wildfires and stratospheric O_3 intrusions) and O_3 precursors, as well as from manmade international emissions of O_3 precursors. Using the term generically, however, can lead to confusion as to what sources of O_3 are being considered. The PA provides three specific definitions of background O_3: natural background, North American background, and United States background. Natural background (NB) is defined as the O_3 that would exist in the absence of any manmade O_3 precursor emissions. North American background (NAB) is defined as that O_3 that would exist in the absence of any manmade O_3 precursor emissions from North America. U.S. background (USB) is defined as that O_3 that would exist in the absence of any manmade emissions inside the U.S. Because background O_3 is difficult to measure, air quality modeling is conducted to estimate NA, NAB, and USB.

The PA identifies several key findings related to background O_3. First, background O_3 can comprise a considerable fraction of total seasonal mean O_3 across the U.S. Studies have estimated that seasonal mean USB 8-hour O_3 values across U.S. locations varied between 25 to 50 ppb in 2007 (U.S. EPA, 2014c, Figure 211). The largest seasonal average values of background are modeled to occur at locations in the intermountain western U.S. and the highest daily USB levels are highest in the spring and early summer seasons. Second, the modeling indicates that U.S. anthropogenic emission sources are the dominant contributor to the majority of modeled O_3 exceedances of the NAAQS across the U.S. This conclusion is based on results that indicate background contributions are generally similar on high O_3 days as on all other O_3 days. As a result, the proportional influence of background sources tends to be lower on high O_3 days. Third, while the majority of modeled O_3 exceedances have local and regional emissions as their primary cause, there can be events where O_3 levels approach or exceed the concentration levels being proposed in this notice (*i.e.,* 60–70 ppb) in large part due to background sources. These cases of high USB levels on high O_3 days typically result from stratospheric intrusions of O_3, wildfire O_3 plumes, or long-range transport of O_3 from sources outside the U.S. In most locations in the U.S., these events are relatively infrequent and the CAA contains provisions that can be used to help deal with certain events, including providing varying degrees of regulatory relief for air agencies and potential regulated entities.

Regulatory relief associated with U.S. background O_3 may include: [271]

[271] Note that the relief mechanisms discussed here do not include the CAA's interstate transport provisions found in sections 110(a)(2)(D) and 126. The interstate transport provisions are intended to address the cross-state transport of O_3 and O_3 precursor emissions from man-made sources within

• Relief from designation as a nonattainment area (through exclusion of data affected by exceptional events)
• Relief from the more stringent requirements of higher nonattainment area classifications (through treatment as a rural transport area; through exclusion of data affected by exceptional events; or through international transport provisions)
• Relief from adopting more than reasonable controls to demonstrate attainment (through international transport provisions)

None of these relief mechanisms are completely burden-free, meaning they all require some level of assessment or demonstration by a state and/or EPA to legally invoke. In no case does the CAA authorize a blanket exclusion from the basic application of an air quality management regime because an area is significantly impacted by background O_3. While any prediction of the exact nature of future implementation challenges associated with alternative prospective standards is inherently uncertain, there is no question that, as the levels of alternative prospective standards are lowered, background will represent increasingly larger fractions of total O_3 levels and may subsequently complicate efforts to attain these standards. For a prospective standard of 70 ppb, the EPA does not believe that background O_3 would create significant implementation-related challenges at locations throughout the U.S. and prevent attainment of the NAAQS. However, as the levels of prospective standards are lowered, the areas that would most likely need to use the relief mechanisms discussed in this section as part of attaining the lower prospective levels are rural locations in the western U.S., consistent with the previously mentioned locations where we have estimated the largest seasonal average values of background occur. The remainder of this section discusses these relief mechanisms and the methods associated with legally invoking them. These relief mechanisms depend on distinguishing background O_3 by the following types of drivers: routine natural emissions, non-routine natural events and international emissions. The EPA welcomes comment on any of these issues related to O_3 background and implementation.

2. Exceptional Events Exclusions

A state can request and the EPA can agree to exclude data associated with event-influenced exceedances or violations of a NAAQS, including the proposed O_3 NAAQS, provided the event meets the statutory requirements in section 319 of the CAA:

• The event ''affects air quality.''
• The event ''is not reasonably controllable or preventable.''
• The event is ''caused by human activity that is unlikely to recur at a particular location or [is] a natural event.'' [272]

The EPA's implementing regulations, the 2007 Exceptional Events Rule, further specify that states must provide evidence that: [273]

• ''There is a clear causal relationship between the measurement under consideration and the event that is claimed to have affected the air quality in the area;''
• ''The event is associated with a measured concentration in excess of normal historical fluctuations, including background;'' and
• ''There would have been no exceedance or violation but for the event.''

The ISA contains discussions of natural events that may contribute to O_3 or O_3 precursors. These include stratospheric O_3 intrusion and wildfire events.[274] As indicated above, to satisfy the exceptional event requirements and to qualify for data exclusion under the Exceptional Events Rule, a state must develop and submit evidence addressing each of the identified criteria. The extent to which a stratospheric O_3 intrusion event or a wildfire event contribute to O_3 levels can be uncertain, and in most cases requires detailed investigation and analysis to adequately determine.

Strong stratospheric O_3 intrusion events, most prevalent at high elevation sites during winter or spring, can be identified based on measurements of low relative humidity, evidence of deep atmospheric mixing, and a low ratio of CO to O_3 based on ambient measurements. Accurately determining the extent of weaker intrusion events remains challenging (U.S. EPA 2013a, p. 3–34). Although states have submitted only a few exceptional event demonstrations for stratospheric O_3 intrusion, the EPA recently approved a demonstration from Wyoming for a June 2012 stratospheric O_3 event.[275]

While stratospheric O_3 intrusions can increase monitored ground-level ambient O_3 concentrations, wildfire plumes can either suppress or enhance O_3 depending upon a variety of factors including fuel type, combustion stage, plume chemistry, aerosol effects, meteorological conditions and distance from the fire (Jaffe and Wigder, 2012). As such, determining the impact of wildfire emissions on specific O_3 observations is challenging. The EPA recently approved an exceptional event demonstration for wildfires affecting 1-hour O_3 levels in Sacramento, California in 2008 that successfully used a variety of analytical tools (*e.g.,* regression modeling, back trajectories, satellite imagery, etc.) to support the exclusion of O_3 data affected by large fires.[276]

Because of previously expressed stakeholder feedback regarding implementation of the Exceptional Events Rule and specific stakeholder concerns regarding the analyses that can be used to support O_3-related exceptional event demonstrations, the EPA intends to propose revisions to the Exceptional Events Rule in a future notice and comment rulemaking effort and will solicit public comment at that time.

Additionally, the EPA intends to develop guidance to address implementing the Exceptional Events Rule criteria for wildfires that could affect ambient O_3 concentrations. Wildfire emissions are a component of background O_3 (Jaffe and Wigder, 2012) and can significantly contribute to periodic high O_3 levels (Emery, 2012). Besides their effect on air quality, wildfires pose a direct threat to public safety—a threat that can be mitigated through management of wildland vegetation. Attempts to suppress wildfires have resulted in unintended consequences, including increased risks to both humans and ecosystems. Indeed, ''Fire policy that focuses on [wildfire] suppression only, delays the inevitable, promising more dangerous and destructive future . . . fires'' (Stephens, S. et al., 2013). The use of wildland

the continental U.S. rather than background O_3 as it is defined in this section.

[272] A natural event is further described in 40 CFR 50.1(k) as ''an event in which human activity plays little or no direct causal role.''

[273] **Federal Register** (2007). Treatment of Data Influenced by Exceptional Events; Final Rule. 40 CFR 50 and 51; **Federal Register** 72:13560.

[274] The preamble to the Exceptional Events Rule (72 FR 13560, March 22, 2007) identifies both stratospheric O_3 intrusions and wildfires as natural events that could also qualify as exceptional events under the CAA and Exceptional Event Rule criteria. Note that O_3 resulting from routine natural emissions from vegetation, microbes, animals and lightning are not exceptional events authorized for exclusion under the section 319 of the CAA.

[275] U.S. EPA (2014) Treatment of Data Influenced by Exceptional Events: Examples of Reviewed Exceptional Event Submissions. U.S. Environmental Protection Agency, Research Triangle Park, NC. Available at *http://www.epa.gov/ttn/analysis/exevents.htm.*

[276] U.S. EPA (2014) Treatment of Data Influenced by Exceptional Events: Examples of Reviewed Exceptional Event Submissions. U.S. Environmental Protection Agency, Research Triangle Park, NC. Examples of O_3-related exceptional event submissions available at *http://www.epa.gov/ttn/analysis/exevents.htm.*

prescribed fire can influence the occurrence of catastrophic wildfires which may help manage the contribution of wildfires to background O_3 levels and periodic peak O_3 events. Additionally prescribed fires can have benefits to those plant and animal species that depend upon natural fires for propagation, habitat restoration, and reproduction, as well as myriad ecosystem functions (*e.g.,* carbon sequestration). As previously indicated, the CAA and the EPA's implementing regulations allow for the exclusion of air quality monitoring data from design value calculations when they are substantially affected by certain background influences. Additionally, the CAA requires the EPA to set the NAAQS at levels requisite to protect public health and welfare without regard to the source of the pollutant. However, EPA understands the importance of prescribed fire which mimics a natural process necessary to manage and maintain fire-adapted ecosystems and climate change adaptation, while reducing risk of uncontrolled emissions from catastrophic wildfires. The EPA is committed to working with federal land managers, tribes, and states to effectively manage prescribed fire use to reduce the impact of wildland-fire related emissions on ozone through policies and regulations implementing these standards.

3. Rural Transport Areas

Clean Air Act section 182(h) authorizes the EPA Administrator to determine that an area designated nonattainment can be treated as a rural transport area. In accordance with the statute, a nonattainment area may qualify for this determination if it meets the following criteria:

- The area does not contain emissions sources that make a significant contribution to monitored O_3 concentrations in the area, or in other areas; and
- The area does not include and is not adjacent to a Metropolitan Statistical Area.[277]

Historically, the EPA has recognized few nonattainment areas under this statutory provision.[278] The EPA has not issued separate written guidance to further elaborate on the interpretation of these CAA qualification criteria. However, the EPA developed draft guidance in 2005 that explains the kinds of technical analyses that states could use to establish that transport of O_3 and/or O_3 precursors into the area is so overwhelming that the contribution of local emissions to an observed 8-hour O_3 concentration above the level of the NAAQS is relatively minor and determine that emissions within the area do not make a significant contribution to the O_3 concentrations measured in the area or in other areas.[279] While this guidance was not prepared specifically for rural transport areas, it could be useful to states for developing technical information to support a request that the EPA treat a specific O_3 nonattainment area as a rural transport area.

An area that qualifies for treatment as a rural transport area is deemed to have fulfilled all O_3-related planning and control requirements if it meets the CAA's requirements for areas classified Marginal, which is the lowest classification specified in the CAA. Therefore, a state would not need to develop an attainment plan or an attainment demonstration for such an area or adopt the various mandatory measures required in nonattainment areas classified as Moderate or above. The only requirements that would apply, regardless of the level of O_3 air quality, would be NNSR (at the Marginal major source threshold and offset ratio), conformity requirements associated with a nonattainment designation, and the emission inventory and source emission statement requirements.

4. International Transport

Clean Air Act section 179B recognizes the possibility that certain nonattainment areas may be heavily impacted by O_3 or O_3 precursor emissions from international sources beyond the regulatory jurisdiction of the state. The EPA's science review suggests that the influence of international sources on U.S. O_3 levels will be largest in locations that are in the immediate vicinity of an international border with Canada or Mexico, but other locations can also potentially be affected when conditions are favorable for long-range transport (U.S. EPA 2013a, p.3–140). Section 179B allows states to consider in their attainment demonstrations whether an area might have met the O_3 NAAQS by the attainment date ''but for'' emissions contributing to the area originating outside the U.S. If a state is unable to demonstrate attainment in such an area after adopting all reasonably available control measures (RACM, including RACT, as required by CAA section 182(b)), the EPA can nonetheless approve the CAA-required state attainment plan and demonstration using the authority in section 179B.

When the EPA approves this type of attainment plan, states avoid potential sanctions and FIPs, and there would be no adverse consequence for a finding that the area failed to attain the NAAQS by the relevant attainment date. For example, the area would not be reclassified to the next highest classification or required to implement a section 185 penalty fee program.

Section 179B authority does not allow the EPA to avoid designating an area as nonattainment or for the area to be classified with a lower classification than is indicated by actual air quality. Generally, monitoring data influenced by international transport may not be excluded from regulatory determinations, unless the data are influenced by an excludable exceptional event. Section 179B also does not provide for any relaxation of mandatory emissions control measures (including contingency measures) or the prescribed emissions reductions necessary to achieve RFP.

The EPA's guidance on 'but for' demonstrations involving international emissions indicates that states may want to consider conducting air quality modeling using O_3 episodes that do not involve international transport of emissions (U.S. EPA 1991)[280], running the model with boundary conditions that reflect general U.S. background concentrations, and analyzing monitoring data if a dense network has been established. Additional information that may be helpful at nonattainment areas abutting international borders could include evaluating changes in O_3 with changes in wind direction at monitors near the border, and comparing emissions on both sides of the border. States are encouraged to consult with their EPA Regional Office to establish appropriate

[277] Note that the EPA interprets the rural transport provisions of section 182(h) would not apply to an O_3 monitor that is located in a relatively rural location, but is heavily influenced by short-range upwind contributions from a nearby urbanized area. The EPA will work closely with states to determine whether a particular monitor violating the NAAQS is considered to be affiliated with a nearby urban area, or is an isolated rural area monitor.

[278] For the 1979 1-hour O_3 standard, Essex County, New York, and Smyth County, Virginia (White Top Mountain) were recognized by the EPA as rural transport areas.

[279] U.S. Environmental Protection Agency (2005). Criteria For Assessing Whether an Ozone Nonattainment Area is Affected by Overwhelming Transport [Draft EPA Guidance]. U.S. Environmental Protection Agency, Research Triangle Park, NC. June 2005. Available at *http://www.epa.gov/scram001/guidance/guide/owt_guidance_07-13-05.pdf.*

[280] U.S. Environmental Protection Agency (1991). Criteria for Assessing the Role of Transported Ozone/Precursors in Ozone Nonattainment Areas. EPA–450/4–91–015. U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC. May 1991.

technical requirements for these analyses.

The EPA has used section 179B authority previously to approve attainment plans for Mexican border areas in El Paso, TX (O_3, PM_{10}, and CO plans); Nogales, AZ (PM_{10} plan); and Imperial Valley, CA (PM_{10} plan). The 1-hour O_3 attainment plan for El Paso, TX was approved by EPA as sufficient to demonstrate attainment of the NAAQS by the Moderate classification deadline of November 15, 1996, taking into account ''but for'' international emissions sources in Ciudad Juárez, Mexico (69 FR 32450, June 10, 2004). The state's demonstration included airshed modeling using only the U.S. emissions data because emissions data from Ciudad Juárez were not available.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the document, Regulatory Impact Analysis for the O_3 NAAQS, November, 2014. A copy of the analysis is available in the RIA docket (EPA–HQ–OAR–2013–0169) and the analysis is briefly summarized here. The RIA estimates the costs and monetized human health and welfare benefits of attaining four alternative O_3 NAAQS nationwide. Specifically, the RIA examines the alternatives of 60 ppb, 65 ppb, 70 ppb, and 75 ppb. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that states and Regional Planning Organizations might implement to achieve these alternative O_3 NAAQS. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of state plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this proposed rule.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR #2313.03. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health and ecosystems impacts, to develop emission control strategies, and to measure progress for the air pollution program. We are proposing to extend the length of the required O_3 monitoring season in 33 states and propose that the revised O_3 monitoring seasons become effective on January 1, 2017. We are also proposing revisions to the PAMS monitoring requirements that reduce the number of required PAMS sites while improving spatial coverage, and proposing to require states with O_3 non-attainment areas to develop an enhanced monitoring plan as part of the PAMS requirements. For areas currently designated as nonattainment for O_3 based on the 2008 NAAQS, we propose that these areas comply with the PAMS requirements by June 1, 2017. For new areas designated based on a revised NAAQS, if finalized, we propose that those areas comply with the PAMS requirements by January 1, 2019. In addition, we are proposing to revise the O_3 FRM to establish a new, additional technique for measuring O_3 in the ambient air. We propose that it be incorporated into the existing O_3 FRM, using the same calibration procedure in Appendix D of 40 CFR part 50. We also propose to make changes to the procedures for testing performance characteristics and determining comparability between candidate FEMs and reference methods.

For the purposes of ICR #2313.03, the burden figures represent the burden estimate based on the requirements contained in the proposed rule. The burden estimates are for the 3-year period from 2015 through 2017. The implementation of the PAMS changes, if finalized, will occur beyond the time frame of this ICR with likely implementation dates between 2017 and 2019. The cost estimates for the PAMS network (including proposed revisions) will be captured in future routine updates to the Ambient Air Quality Surveillance ICR that are required every 3 years by OMB. The proposal for a new FRM in 40 CFR part 50 and revisions to the O_3 FEM procedures for testing performance characteristics in 40 CFR part 53 does not add any additional information collection requirements.

The ICR burden estimates are associated with the proposed changes to the O_3 seasons. This information collection is estimated to involve 158 respondents for a total cost of approximately $24,115,182 (total capital, labor, and operation and maintenance) plus a total burden of 339,930 hours for the support of all operational aspects of the entire O_3 monitoring network. The labor costs associated with these hours are $19,813,692. Also included in the total are other costs of operations and maintenance of $2,210,132 and equipment and contract costs of $2,091,358. The actual labor cost increase to expand the O_3 monitoring seasons is $1,668,433. In addition to the costs at the state, local, and tribal air quality management agencies, there is a burden to EPA of 41,418 hours and $2,617,591. Burden is defined at 5 CFR 1320.3(b). State, local, and tribal entities are eligible for state assistance grants provided by the Federal government under the CAA which can be used for related activities. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2008–0699. Submit any comments related to the ICR to EPA and OMB. Send comments to the EPA at the Air and Radiation Docket and Information Center Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center Docket is (202) 566–1742. An electronic version of the public docket is available at *www.regulations.gov*. Send comments to OMB at the Office of

Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after December 17, 2014, a comment to OMB is best assured of having its full effect if OMB receives it by December 17, 2014. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

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 (RFA). The reason is that this proposed rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of O_3 in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA,* 175 F. 3d at 1044–45 (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the proposed revisions to 40 CFR part 58 address the requirements for states to collect information and report compliance with the NAAQS and will not impose any requirements on small entities. Similarly, the addition of a new FRM in 40 CFR part 50 and revisions to the FEM procedures for testing in 40 CFR part 53 will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate as described in the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531—1538, and does not significantly or uniquely affect small governments. Furthermore, as indicated previously, in setting a NAAQS the EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of state plans to implement the standards. See also *American Trucking Associations* v. *EPA,* 175 F. 3d at 1043 (noting that because the EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis (RIA) pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS).

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 does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes as tribes are not obligated to adopt or implement any NAAQS. In addition, tribes are not obligated to conduct ambient monitoring for O_3 or to adopt the ambient monitoring requirements of 40 CFR part 58. Thus, Executive Order 13175 does not apply to this rule.

The EPA specifically solicits comment on this rule from tribal officials. Prior to finalization of this proposal, the EPA intends to conduct outreach consistent with the EPA Policy on Consultation and Coordination with Indian Tribes. Outreach to tribal environmental professionals will be conducted through participation in the Tribal Air call, which is sponsored by the National Tribal Air Association. In addition, the EPA intends to offer formal consultation to the tribes during the public comment period. If consultation is requested, a summary of the result of that consultation will be presented in the notice of final rulemaking and will be available in the docket.

G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks

This action is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health risk addressed by this action may have a disproportionate effect on children. The rule will establish uniform national ambient air quality standards for O_3; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because children, especially children with asthma, along with other at-risk populations[281] such as all people with lung disease and people active outdoors, are potentially susceptible to health effects resulting from O_3 exposure. Because children are considered an at-risk lifestage, we have carefully evaluated the environmental health effects of exposure to O_3 pollution among children. Discussions of the results of the evaluation of the scientific evidence, policy considerations, and the exposure and risk assessments pertaining to children are contained in sections II.B and II.C of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for O_3, establish an additional FRM, revise FEM procedures for testing, and revises air quality surveillance requirements. The rule does not prescribe specific pollution control strategies by which these ambient standards and monitoring revisions will be met. Such strategies will be developed by states on a case-by-case basis, and the EPA cannot predict whether the control options selected by states will include regulations on energy suppliers, distributors, or users. Thus, the EPA concludes that this rule is not likely to have any adverse energy effects and does not constitute a significant energy action as defined in Executive Order 13211.

I. National Technology Transfer and Advancement Act

This rulemaking involves environmental monitoring and measurement. Consistent with the Agency's Performance Based Measurement System (PBMS), the EPA proposes not to require the use of specific, prescribed analytical methods. Rather, the Agency plans to allow the use of any method that meets the prescribed performance criteria. Ambient air concentrations of ozone are currently measured by the Federal reference method (FRM) in 40 CFR part 50, Appendix D (Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere) or by Federal equivalent methods (FEM) that meet the requirements of 40 CFR part 53. Procedures are available in part 53 that

[281] As used here and similarly throughout this document, the term population refers to people having a quality or characteristic in common, including a specific pre-existing illness or a specific age or life stage.

allow for the approval of an FEM for O_3 that is similar to the FRM. Any method that meets the performance criteria for a candidate equivalent method may be approved for use as an FEM. This approach is consistent with EPA's PBMS. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. The EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

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 potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations because it does not affect the level of protection provided to human health or the environment. This action proposes the strengthening of the O_3 NAAQS. If the proposed revisions are finalized, the revised O_3 NAAQS will increase public health protection. Analyses evaluating the potential implications of a revised O_3 NAAQS for environmental justice populations are discussed in appendix 9A of the Regulatory Impact Analysis (RIA) that accompanies this notice of proposed rulemaking. The RIA is available on the Web, through the EPA's Technology Transfer Network Web site at *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html*.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 51

Environmental protection, Administrative practices and procedures, Air pollution control, Intergovernmental relations.

40 CFR Part 52

Environmental Protection, Administrative practices and procedures, Air pollution control, Incorporation by reference, Intergovernmental relations.

40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

40 CFR Part 58

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

Dated: November 25, 2014.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

■ 1. The authority citation for part 50 continues to read as follows:

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

■ 2. Amend § 50.14 by:

■ a. Revising paragraph (c)(2)(iii);

■ b. Removing and reserving paragraphs (c)(2)(iv) and (v);

■ c. Revising paragraph (c)(2)(vi) introductory text and Table 1;

■ d. Revising paragraph (c)(3)(i); and

■ e. Removing and reserving paragraphs (c)(3)(ii) and (iii);

■ 3. The revisions read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *

(c) * * *

(2) * * *

(iii) Flags placed on data as being due to an exceptional event together with an initial description of the event shall be submitted to EPA not later than July 1st of the calendar year following the year in which the flagged measurement occurred, except as allowed under paragraph (c)(2)(vi) of this section.

* * * * *

(vi) Table 1 identifies the data submission process for new or revised NAAQS, beginning with the 2015 Ozone NAAQS. This process shall apply to those data that will or may influence the initial designation of areas for any new or revised NAAQS.

TABLE 1—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN INITIAL AREA DESIGNATIONS

Exceptional event/regulatory action	Exceptional event deadline schedule [d]
Exceptional event data flagging and initial description deadline for data years 1, 2 and 3.[a]	If state and tribal recommendations for the new/revised NAAQS are due August through January, then the flagging and initial description deadline will be the July 1 prior to the recommendation deadline. If state and tribal recommendations for the new/revised NAAQS are due February through July, then the flagging and initial description deadline will be the January 1 prior to the recommendation deadline.
Exceptional event demonstration submittal deadline for data years 1, 2 and 3.[a]	No later than the date that state and tribal recommendations are due to EPA.
Exceptional event data flagging, initial description, and exceptional event demonstration submittal deadline for data year 4 [b] and potential data year 5.[c]	By the last day of the month that is 1 year and 7 months after promulgation of a new or revised NAAQS, unless either option a or b applies. a. If the EPA follows a 3-year designation schedule, the deadline is 2 years and 7 months after promulgation of a new or revised NAAQS. b. If the EPA notifies the state/tribe via **Federal Register** notice, letter or guidance that it intends to complete the initial area designations process according to a schedule other than a 2-year or 3-year timeline, the deadline is 5 months prior to the date specified for final designations decisions in such EPA notification.

[a] Where data years 1, 2, and 3 are those years expected to be considered in state and tribal recommendations.

[b] Where data year 4 is the additional year of data that the EPA may consider when it makes final area designations for the new/revised NAAQS under a 2-year designations schedule.

[c] Where data year 5 is the additional year of data that the EPA may consider when it makes final area designations for the new/revised NAAQS under an extended designations schedule.

[d] The date by which air agencies must certify their ambient air quality monitoring data in AQS is annually on May 1 of the year following the year of data collection. The EPA cannot require air agencies to certify data prior to this date. In some cases, however, air agencies may choose to certify a prior year's data in advance of May 1 of the following year, particularly if the EPA has indicated its intent to promulgate final designations in the months of May, June, July or August. Exceptional event flagging, initial description, and demonstration deadlines for ''early certified'' data will follow the deadlines for ''year 4'' and ''year 5'' data.

(3) *Submission of demonstrations.* (i) Except as allowed under paragraph (c)(2)(vi) of this section, a State that has flagged data as being due to an exceptional event and is requesting exclusion of the affected measurement data shall, after notice and opportunity for public comment, submit a demonstration to justify data exclusion to EPA not later than the lesser of, 3 years following the end of the calendar quarter in which the flagged concentration was recorded or, 12 months prior to the date that a regulatory decision must be made by EPA. A State must submit the public comments it received along with its demonstration to EPA.

* * * * *

■ 3. Section 50.19 is added to read as follows:

§ 50.19 National primary and secondary ambient air quality standards for ozone.

(a) The level of the national 8-hour primary ambient air quality standard for ozone (O_3) is (0.065–0.070) parts per million (ppm), daily maximum 8-hour average, measured by a reference method based on appendix D to this part and designated in accordance with part 53 of this chapter or an equivalent method designated in accordance with part 53 of this chapter.

(b) The 8-hour primary O_3 ambient air quality standard is met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3

concentration is less than or equal to (0.065–0.070) ppm, as determined in accordance with appendix U to this part.

(c) The level of the national secondary ambient air quality standard for O_3 is (0.065–0.070) ppm, daily maximum 8-hour average, measured by a reference method based on appendix D to this part and designated in accordance with part 53 of this chapter or an equivalent method designated in accordance with part 53 of this chapter.

(d) The 8-hour secondary O_3 ambient air quality standard is met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is less than or equal to (0.065–0.070) ppm, as determined in accordance with appendix U to this part.

■ 4. Revise appendix D to part 50 under subchapter C to read as follows:

Appendix D to Part 50—Reference Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere (Chemiluminescence Method)

1.0 *Applicability.*

1.1 This chemiluminescence method provides reference measurements of the concentration of ozone (O_3) in ambient air for determining compliance with the national primary and secondary ambient air quality standards for O_3 as specified in 40 CFR part 50. This automated method is applicable to the measurement of ambient O_3 concentrations using continuous (real-time) sampling and analysis. Additional quality assurance procedures and guidance are provided in 40 CFR part 58, appendix A, and in Reference 14.

2.0 *Measurement Principle.*

2.1 This reference method is based on continuous automated measurement of the intensity of the characteristic chemiluminescence released by the gas phase reaction of O_3 in sampled air with either ethylene (C_2H_4) or nitric oxide (NO) gas. An ambient air sample stream and a specific flowing concentration of either C_2H_4 (ET–CL method) or NO (NO–CL method) are mixed in a measurement cell, where the resulting chemiluminescence is quantitatively measured by a sensitive photo-detector. References 8–11 describe the chemiluminescence measurement principle.

2.2 The measurement system is calibrated by referencing the instrumental chemiluminescence measurements to certified O_3 standard concentrations generated in a dynamic flow system and assayed by photometry to be traceable to a National Institute of Standards and Technology (NIST) standard reference photometer for O_3 (see Section 4, Calibration Procedure, below).

2.3 An analyzer implementing this measurement principle is shown schematically in Figure 1. Designs implementing this measurement principle must include: An appropriately designed mixing and measurement cell; a suitable quantitative photometric measurement system with adequate sensitivity and wave length specificity for O_3; a pump, flow control, and sample conditioning system for sampling and drying the ambient air and moving it into and through the measurement cell; a means to supply, meter, and mix a constant, flowing stream of either C_2H_4 or NO gas of fixed concentration with the sample air flow in the measurement cell; suitable electronic control and measurement processing capability; and other associated apparatus as may be necessary. The analyzer must be designed and constructed to provide accurate, repeatable, and continuous measurements of O_3 concentrations in ambient air, with measurement performance that meets the requirements specified in subpart B of part 53 of this chapter.

2.4 An analyzer implementing this measurement principle and calibration procedure will be considered a federal reference method (FRM) only if it has been designated as a reference method in accordance with part 53 of this chapter.

2.5 *Sampling considerations.* The use of a particle filter on the sample inlet line of a chemiluminescence O_3 FRM analyzer is required to prevent buildup of particulate matter in the measurement cell and inlet components. This filter must be changed weekly (or at least often as specified in the manufacturer's operation/instruction manual), and the sample inlet system used with the analyzer must be kept clean, to avoid loss of O_3 in the O_3 sample air prior to the concentration measurement.

3.0 *Interferences.*

3.1 Except as described in 3.2 below, the chemiluminescence measurement system is inherently free of significant interferences from other pollutant substances that may be present in ambient air.

3.2 A small sensitivity to variations in the humidity of the sample air is minimized by a sample air dryer. Potential loss of O_3 in the inlet air filter and in the air sample handling components of the analyzer and associated exterior air sampling components due to buildup of airborne particulate matter is minimized by filter replacement and cleaning of the other inlet components.

4.0 *Calibration Procedure.*

4.1 *Principle.* The calibration procedure is based on the photometric assay of O_3 concentrations in a dynamic flow system. The concentration of O_3 in an absorption cell is determined from a measurement of the amount of 254 nm light absorbed by the sample. This determination requires knowledge of (1) the absorption coefficient (α) of O_3 at 254 nm, (2) the optical path length (l) through the sample, (3) the transmittance of the sample at a nominal wavelength of 254 nm, and (4) the temperature (T) and pressure (P) of the sample. The transmittance is defined as the ratio I/I_0, where I is the intensity of light which passes through the cell and is sensed by the detector when the cell contains an O_3 sample, and I_0 is the intensity of light which passes through the cell and is sensed by the detector when the cell contains zero air. It is assumed that all conditions of the system, except for the contents of the absorption cell, are identical during measurement of I and I_0. The quantities defined above are related by the Beer-Lambert absorption law,

$$\text{Transmitance} = \frac{I}{I_0} = e^{-\alpha c l} \qquad (1)$$

Where:

α = absorption coefficient of O_3 at 254 nm = 308 ±4 atm − 1 cm − 1 at 0 °C and 760 torr,[1, 2, 3, 4, 5, 6, 7]

c = O_3 concentration in atmospheres, and

l = optical path length in cm.

A stable O_3 generator is used to produce O_3 concentrations over the required calibration concentration range. Each O_3 concentration is determined from the measurement of the transmittance (I/I_0) of the sample at 254 nm with a photometer of path length l and calculated from the equation,

$$c(\text{atm}) = -\frac{1}{\alpha l}\left(\ln\frac{I}{I_0}\right) \qquad (2a)$$

or

$$c(\text{ppm}) = -\frac{10^6}{\alpha l}\left(\ln\frac{I}{I_0}\right). \qquad (2b)$$

The calculated O_3 concentrations must be corrected for O_3 losses, which may occur in the photometer, and for the temperature and pressure of the sample.

4.2 *Applicability.* This procedure is applicable to the calibration of ambient air O_3 analyzers, either directly or by means of a transfer standard certified by this procedure. Transfer standards must meet the requirements and specifications set forth in Reference 12.

4.3 *Apparatus.* A complete UV calibration system consists of an O_3 generator, an output port or manifold, a photometer, an appropriate source of zero air, and other components as necessary. The configuration must provide a stable O_3 concentration at the system output and allow the photometer to accurately assay the output concentration to the precision specified for the photometer (4.3.1). Figure 2 shows a commonly used configuration and serves to illustrate the calibration procedure, which follows. Other configurations may require appropriate variations in the procedural steps. All connections between components in the calibration system downstream of the O_3 generator must be of glass, Teflon, or other relatively inert materials. Additional information regarding the assembly of a UV photometric calibration apparatus is given in Reference 13. For certification of transfer standards which provide their own source of O_3, the transfer standard may replace the O_3 generator and possibly other components shown in Figure 2; see Reference 12 for guidance.

4.3.1 *UV photometer.* The photometer consists of a low-pressure mercury discharge lamp, (optional) collimation optics, an absorption cell, a detector, and signal-processing electronics, as illustrated in Figure 2. It must be capable of measuring the transmittance, I/I_0, at a wavelength of 254 nm with sufficient precision such that the standard deviation of the concentration measurements does not exceed the greater of 0.005 ppm or 3% of the concentration. Because the low-pressure mercury lamp radiates at several wavelengths, the photometer must incorporate suitable means to assure that no O_3 is generated in the cell by the lamp, and that at least 99.5% of the radiation sensed by the detector is 254 nm radiation. (This can be readily achieved by prudent selection of optical filter and detector response characteristics.) The length of the light path through the absorption cell must be known with an accuracy of at least 99.5%. In addition, the cell and associated plumbing must be designed to minimize loss of O_3 from contact with cell walls and gas handling components. See Reference 13 for additional information.

4.3.2 *Air flow controllers.* Air flow controllers are devices capable of regulating air flows as necessary to meet the output stability and photometer precision requirements.

4.3.3 *Ozone generator.* The ozone generator used must be capable of generating stable levels of O_3 over the required concentration range.

4.3.4 *Output manifold.* The output manifold must be constructed of glass, Teflon, or other relatively inert material, and should be of sufficient diameter to insure a negligible pressure drop at the photometer connection and other output ports. The system must have a vent designed to insure atmospheric pressure in the manifold and to prevent ambient air from entering the manifold.

4.3.5 *Two-way valve.* A manual or automatic two-way valve, or other means is used to switch the photometer flow between zero air and the O_3 concentration.

4.3.6 *Temperature indicator.* A device to indicate temperature must be used that is accurate to ±1 °C.

4.3.7 *Barometer or pressure indicator.* A device to indicate barometric pressure must be used that is accurate to ±2 torr.

4.4 *Reagents.*

4.4.1 *Zero air.* The zero air must be free of contaminants which would cause a detectable response from the O_3 analyzer, and it must be free of NO, C_2H_4, and other species which react with O_3. A procedure for generating suitable zero air is given in Reference 13. As shown in Figure 2, the zero air supplied to the photometer cell for the I_0 reference measurement must be derived from the same source as the zero air used for generation of the O_3 concentration to be assayed (I measurement). When using the photometer to certify a transfer standard having its own source of O_3, see Reference 12 for guidance on meeting this requirement.

4.5 *Procedure.*

4.5.1 *General operation.* The calibration photometer must be dedicated exclusively to use as a calibration standard. It must always be used with clean, filtered calibration gases, and never used for ambient air sampling. A number of advantages are realized by locating the calibration photometer in a clean laboratory where it can be stationary, protected from the physical shock of transportation, operated by a responsible analyst, and used as a common standard for all field calibrations via transfer standards.

4.5.2 *Preparation.* Proper operation of the photometer is of critical importance to the accuracy of this procedure. Upon initial operation of the photometer, the following steps must be carried out with all quantitative results or indications recorded in a chronological record, either in tabular form or plotted on a graphical chart. As the performance and stability record of the photometer is established, the frequency of these steps may be reduced to be consistent with the documented stability of the photometer and the guidance provided in Reference 12.

4.5.2.1 *Instruction manual.* Carry out all set up and adjustment procedures or checks as described in the operation or instruction manual associated with the photometer.

4.5.2.2 *System check.* Check the photometer system for integrity, leaks, cleanliness, proper flow rates, etc. Service or replace filters and zero air scrubbers or other consumable materials, as necessary.

4.5.2.3 *Linearity.* Verify that the photometer manufacturer has adequately established that the linearity error of the photometer is less than 3%, or test the linearity by dilution as follows: Generate and assay an O_3 concentration near the upper range limit of the system or appropriate calibration scale for the instrument, then accurately dilute that concentration with zero air and re-assay it. Repeat at several different dilution ratios. Compare the assay of the original concentration with the assay of the diluted concentration divided by the dilution ratio, as follows

$$E = \frac{A_1 - A_2/R}{A_1} \times 100\% \qquad (3)$$

Where:

E = linearity error, percent

A_1 = assay of the original concentration

A_2 = assay of the diluted concentration

R = dilution ratio = flow of original concentration divided by the total flow

The linearity error must be less than 5%. Since the accuracy of the measured flow-rates will affect the linearity error as measured this way, the test is not necessarily conclusive. Additional information on verifying linearity is contained in Reference 13.

4.5.2.4 *Inter-comparison.* The photometer must be inter-compared annually, either directly or via transfer standards, with a NIST standard reference photometer (SRP) or calibration photometers used by other agencies or laboratories.

4.5.2.5 *Ozone losses.* Some portion of the O_3 may be lost upon contact with the photometer cell walls and gas handling components. The magnitude of this loss must be determined and used to correct the calculated O_3 concentration. This loss must not exceed 5%. Some guidelines for quantitatively determining this loss are discussed in Reference 13.

4.5.3 *Assay of O_3 concentrations.* The operator must carry out the following steps to properly assay O_3 concentrations.

4.5.3.1 Allow the photometer system to warm up and stabilize.

4.5.3.2 Verify that the flow rate through the photometer absorption cell, F, allows the cell to be flushed in a reasonably short period of time (2 liter/min is a typical flow). The precision of the measurements is inversely related to the time required for flushing, since the photometer drift error increases with time.

4.5.3.3 Ensure that the flow rate into the output manifold is at least 1 liter/min greater than the total flow rate required by the photometer and any other flow demand connected to the manifold.

4.5.3.4 Ensure that the flow rate of zero air, Fz, is at least 1 liter/min greater than the flow rate required by the photometer.

4.5.3.5 With zero air flowing in the output manifold, actuate the two-way valve to allow the photometer to sample first the manifold zero air, then Fz. The two photometer readings must be equal ($I = I_0$).

Note: In some commercially available photometers, the operation of the two-way valve and various other operations in section 4.5.3 may be carried out automatically by the photometer.

4.5.3.6 Adjust the O_3 generator to produce an O_3 concentration as needed.

4.5.3.7 Actuate the two-way valve to allow the photometer to sample zero air until the absorption cell is thoroughly flushed and record the stable measured value of I_o.

4.5.3.8 Actuate the two-way valve to allow the photometer to sample the O_3 concentration until the absorption cell is thoroughly flushed and record the stable measured value of I.

4.5.3.9 Record the temperature and pressure of the sample in the photometer absorption cell. (See Reference 13 for guidance.)

4.5.3.10 Calculate the O_3 concentration from equation 4. An average of several determinations will provide better precision.

$$[O_3]_{OUT} = \left(\frac{-1}{\alpha l}\ln\frac{I}{I_0}\right)\left(\frac{T}{273}\right)\left(\frac{760}{P}\right)\times\frac{10^6}{L} \quad (4)$$

Where:

$[O_3]_{OUT}$ = O_3 concentration, ppm
α = absorption coefficient of O_3 at 254 nm = 308 atm $-$ 1 cm $-$ 1 at 0 °C and 760 torr
l = optical path length, cm
T = sample temperature, K
P = sample pressure, torr
L = correction factor for O_3 losses from 4.5.2.5 = (1 $-$ fraction of O_3 lost).

Note: Some commercial photometers may automatically evaluate all or part of equation 4. It is the operator's responsibility to verify that all of the information required for equation 4 is obtained, either automatically by the photometer or manually. For ''automatic'' photometers which evaluate the first term of equation 4 based on a linear approximation, a manual correction may be required, particularly at higher O_3 levels. See the photometer instruction manual and Reference 13 for guidance.

4.5.3.11 Obtain additional O_3 concentration standards as necessary by repeating steps 4.5.3.6 to 4.5.3.10 or by Option 1.

4.5.4 *Certification of transfer standards.* A transfer standard is certified by relating the output of the transfer standard to one or more O_3 calibration standards as determined according to section 4.5.3. The exact procedure varies depending on the nature and design of the transfer standard. Consult Reference 12 for guidance.

4.5.5 *Calibration of ozone analyzers.* Ozone analyzers must be calibrated as follows, using O_3 standards obtained directly according to section 4.5.3 or by means of a certified transfer standard.

4.5.5.1 Allow sufficient time for the O_3 analyzer and the photometer or transfer standard to warm-up and stabilize.

4.5.5.2 Allow the O_3 analyzer to sample zero air until a stable response is obtained and then adjust the O_3 analyzer's zero control. Offsetting the analyzer's zero adjustment to +5% of scale is recommended to facilitate observing negative zero drift (if any). Record the stable zero air response as ''Z''.

4.5.5.3 Generate an O_3 concentration standard of approximately 80% of the desired upper range limit (URL) of the O_3 analyzer. Allow the O_3 analyzer to sample this O_3 concentration standard until a stable response is obtained.

4.5.5.4 Adjust the O_3 analyzer's span control to obtain the desired response equivalent to the calculated standard concentration. Record the O_3 concentration and the corresponding analyzer response. If substantial adjustment of the span control is necessary, recheck the zero and span adjustments by repeating steps 4.5.5.2 to 4.5.5.4.

4.5.5.5 Generate additional O_3 concentration standards (a minimum of 5 are recommended) over the calibration scale of the O_3 analyzer by adjusting the O_3 source or by Option 1. For each O_3 concentration standard, record the O_3 concentration and the corresponding analyzer response.

4.5.5.6 Plot the O_3 analyzer responses (vertical or Y-axis) versus the corresponding O_3 standard concentrations (horizontal or X-axis). Compute the linear regression slope and intercept and plot the regression line to verify that no point deviates from this line by more than 2 percent of the maximum concentration tested.

4.5.5.7 *Option 1:* The various O_3 concentrations required in steps 4.5.3.11 and 4.5.5.5 may be obtained by dilution of the O_3 concentration generated in steps 4.5.3.6 and 4.5.5.3. With this option, accurate flow measurements are required. The dynamic calibration system may be modified as shown in Figure 3 to allow for dilution air to be metered in downstream of the O_3 generator. A mixing chamber between the O_3 generator and the output manifold is also required. The flow rate through the O_3 generator (F_o) and the dilution air flow rate (FD) are measured with a flow or volume standard that is traceable to a NIST flow or volume calibration standard. Each O_3 concentration generated by dilution is calculated from:

$$[O_3]'_{OUT} = [O_3]_{OUT}\left(\frac{F_O}{F_O + F_D}\right) \quad (5)$$

Where:

$[O_3]'_{OUT}$ = diluted O_3 concentration, ppm
FO = flow rate through the O_3 generator, liter/min
FD = diluent air flow rate, liter/min

Note: Additional information on calibration and pollutant standards is provided in Section 12 of Reference 14.

5.0 *Frequency of Calibration.*

5.1 The frequency of calibration, as well as the number of points necessary to establish the calibration curve, and the frequency of other performance checking will vary by analyzer; however, the minimum frequency, acceptance criteria, and subsequent actions are specified in Appendix D of Reference 14: Measurement Quality Objectives and Validation Templates. The user's quality control program shall provide guidelines for initial establishment of these variables and for subsequent alteration as operational experience is accumulated. Manufacturers of analyzers should include in their instruction/operation manuals information and guidance as to these variables and on other matters of operation, calibration, routine maintenance, and quality control.

6.0 *References.*

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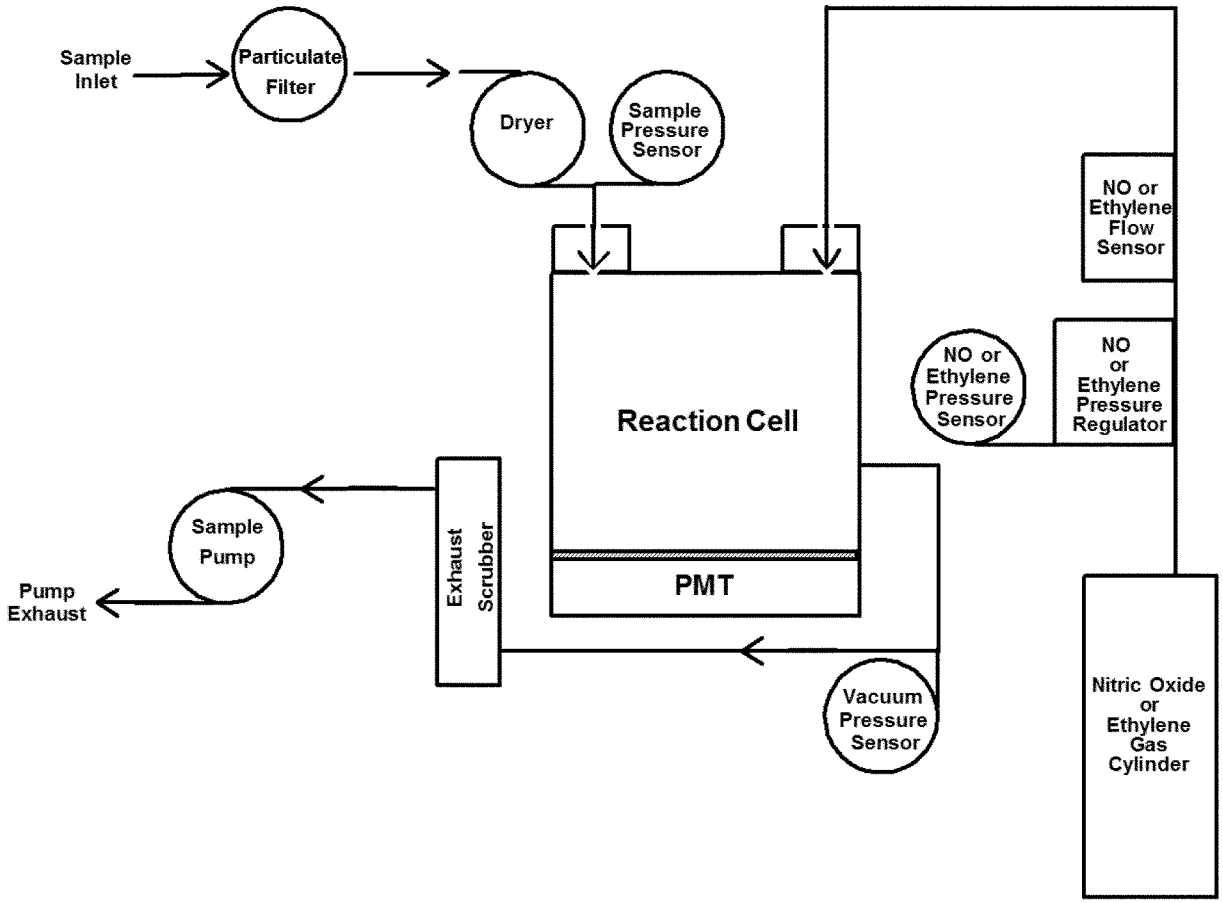


Figure 1. Gas-phase chemiluminescence analyzer schematic diagram, where PMT means photomultiplier tube.

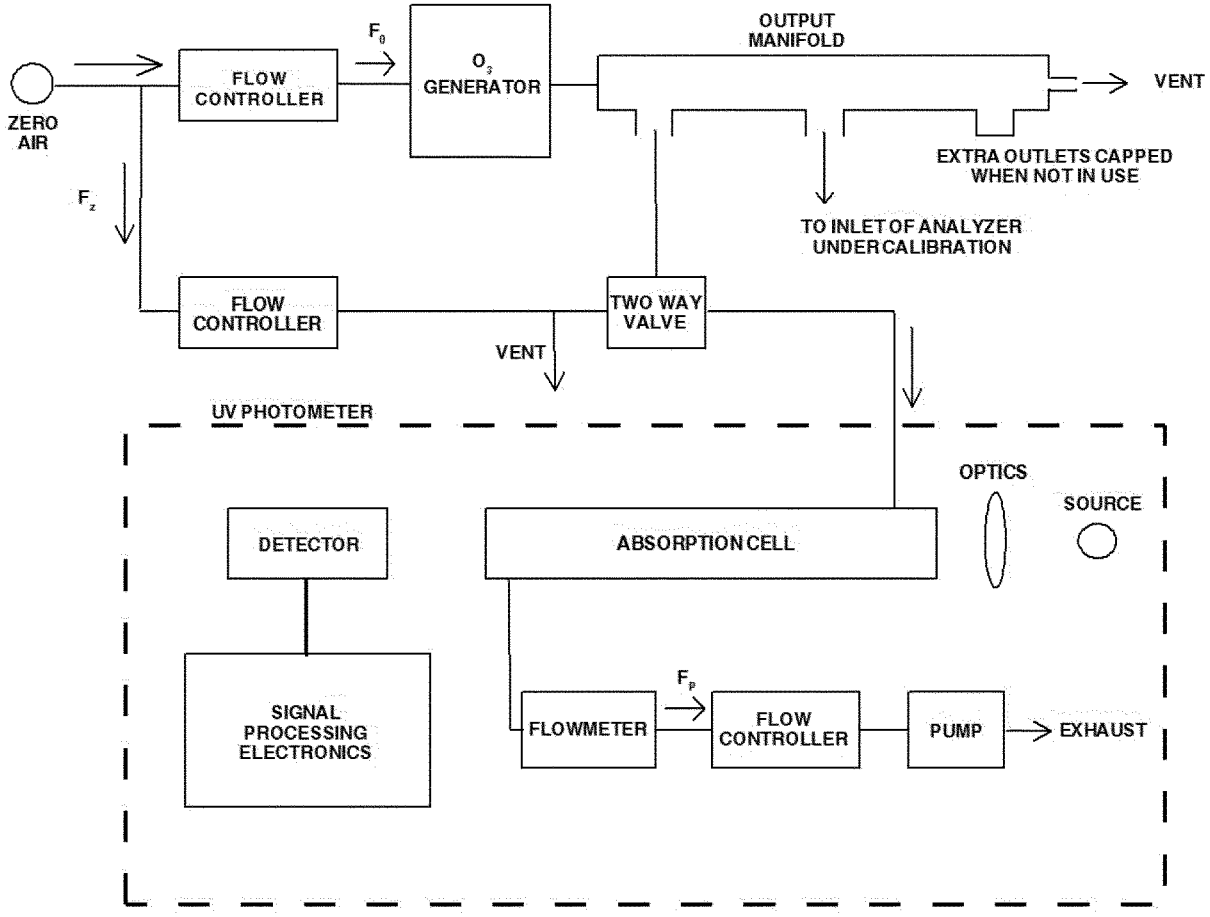
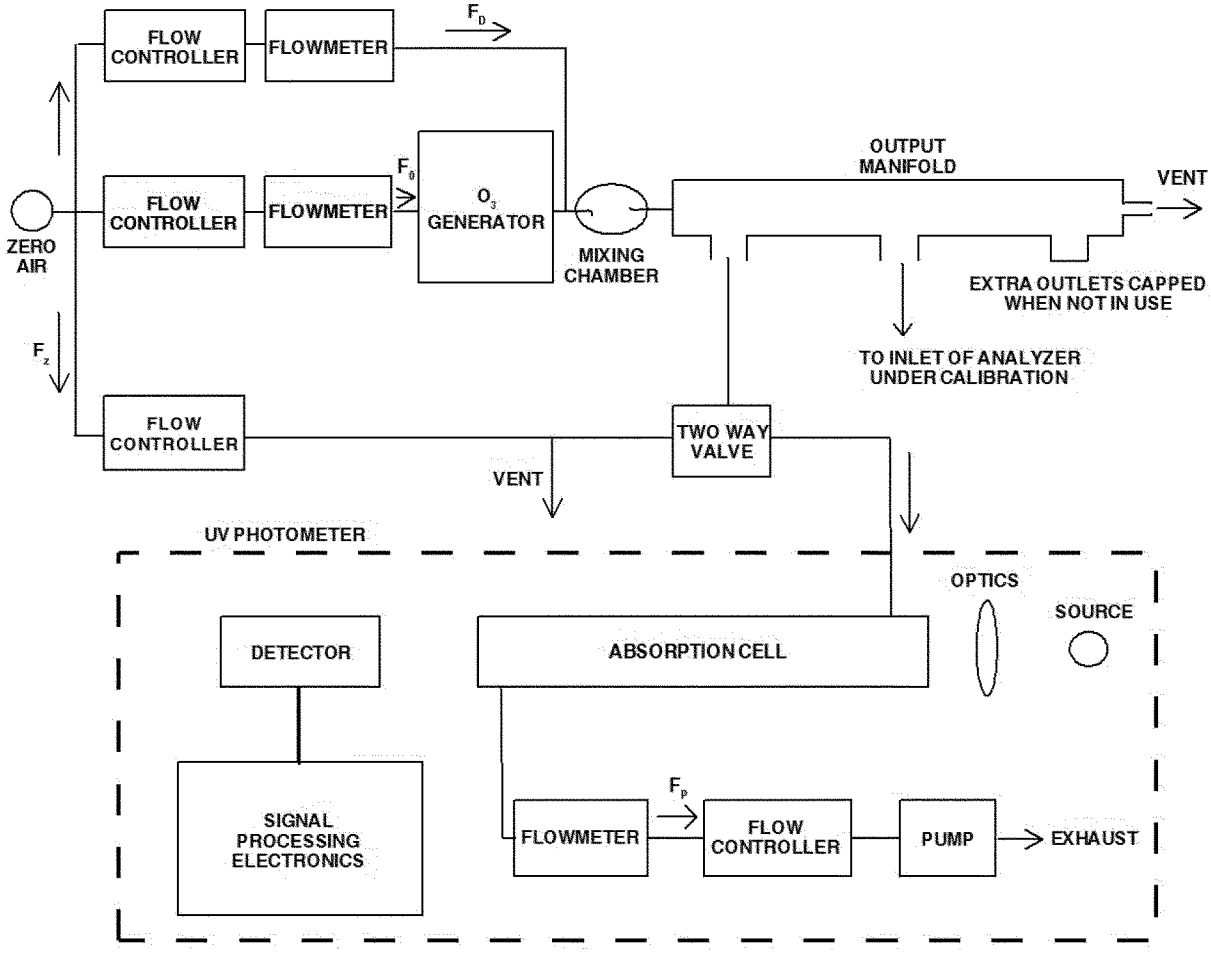


Figure 2. Schematic diagram of a typical UV photometric calibration system.



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■ 5. Appendix U to Part 50 is added to read as follows:

Appendix U to Part 50—Interpretation of the Primary and Secondary National Ambient Air Quality Standards for Ozone

1. *General*

(a) This appendix explains the data handling conventions and computations necessary for determining whether the primary and secondary national ambient air quality standards (NAAQS) for ozone (O_3) specified in § 50.19 are met at an ambient O_3 air quality monitoring site. Data reporting, data handling, and computation procedures to be used in making comparisons between reported O_3 concentrations and the levels of the O_3 NAAQS are specified in the following sections.

(b) Whether to exclude or retain the data affected by exceptional events is determined by the requirements under §§ 50.1, 50.14 and 51.930.

(c) The terms used in this appendix are defined as follows:

8-hour average refers to the moving average of eight consecutive hourly O_3 concentrations measured at a site, as explained in section 3 of this appendix.

Annual fourth-highest daily maximum refers to the fourth highest value measured at a site during a particular year.

Collocated monitors refers to the instance of two or more O_3 monitors operating at the same site.

Daily maximum 8-hour average O_3 concentration refers to the maximum calculated 8-hour average value measured at a site on a particular day, as explained in section 3 of this appendix.

Design value refers to the metric (*i.e.,* statistic) that is used to compare ambient O_3 concentration data measured at a site to the NAAQS in order to determine compliance, as explained in section 4 of this appendix.

Minimum data completeness requirements refer to the amount of data that a site is required to collect in order to make a valid determination that the site is meeting the NAAQS.

Monitor refers to a physical instrument used to measure ambient O_3 concentrations.

O_3 monitoring season refers to the span of time within a year when individual states are required to measure ambient O_3 concentrations, as listed in Appendix D to part 58 of this chapter.

Site refers to an ambient O_3 air quality monitoring site.

Site data record refers to the set of hourly O_3 concentration data collected at a site for use in comparisons with the NAAQS.

Year refers to calendar year.

2. Selection of Data for use in Comparisons With the Primary and Secondary Ozone NAAQS

(a) All valid hourly O_3 concentration data collected using a federal reference method specified in Appendix D to this part, or an equivalent method designated in accordance with part 53 of this chapter, meeting all applicable requirements in part 58 of this chapter, and submitted to EPA's Air Quality System (AQS) database, or otherwise available to EPA, shall be used in design value calculations. Data not meeting these requirements shall not be used in design value calculations.

(b) All design value calculations shall be implemented on a site-level basis. If data are reported to EPA from collocated monitors, those data shall be combined into a single site data record as follows:

(i) The monitoring agency may designate one monitor as the primary monitor for the site. If a primary monitor has not been designated by the monitoring agency, the monitor with the largest number of hourly O_3 concentrations reported for the year shall be designated as the primary monitor.

(ii) Hourly O_3 concentration data from a collocated monitor shall be substituted into the site data record whenever a valid hourly O_3 concentration is not obtained from the primary monitor. In the event that hourly O_3 concentration data are available for two or more collocated monitors, the hourly

concentration data for those monitors shall be averaged and substituted into the site data record.

(c) In certain circumstances, including but not limited to site closures or relocations, data from two nearby sites may be combined into a single site data record for the purpose of calculating a valid design value. The appropriate Regional Administrator may approve such combinations after taking into consideration factors such as distance between sites, spatial and temporal patterns in air quality, local emissions and meteorology, jurisdictional boundaries, and terrain features.

3. Data Reporting and Data Handling Conventions

(a) Hourly average O_3 concentrations shall be reported in parts per million (ppm) to the third decimal place, with additional digits to the right of the third decimal place truncated. Each hour shall be identified using local standard time (LST).

(b) Moving 8-hour averages shall be computed from the hourly O_3 concentration data for each hour of the year and shall be stored in the first, or start, hour of the 8-hour period. An 8-hour average shall be considered valid if at least 6 of the hourly concentrations for the 8-hour period are available. In the event that only 6 or 7 hourly concentrations are available, the 8-hour average shall be computed on the basis of the hours available, using 6 or 7 as the divisor. In addition, in the event that 5 or fewer hourly concentrations are available, the 8-hour average shall be considered valid if, after substituting zero for the missing hourly concentrations, the resulting 8-hour average is greater than the level of the NAAQS. The 8-hour averages shall be reported to three decimal places, with additional digits to the right of the third decimal place truncated. Hourly O_3 concentrations that have been approved under § 50.14 as having been affected by exceptional events shall be counted as missing or unavailable in the calculation of 8-hour averages.

(c) The daily maximum 8-hour average O_3 concentration for a given day is the highest of the 17 consecutive 8-hour averages beginning with the 8-hour period from 7:00 a.m. to 3:00 p.m. and ending with the 8-hour period from 11:00 p.m. to 7:00 a.m. (*i.e.,* the 8-hour averages for 7:00 a.m. to 11:00 p.m.). Daily maximum 8-hour average O_3 concentrations shall be determined for each day with ambient O_3 monitoring data, including days outside the O_3 monitoring season if those data are available.

(d) A daily maximum 8-hour average O_3 concentration shall be considered valid if valid 8-hour averages are available for at least 13 of the 17 consecutive 8-hour periods starting from 7:00 a.m. to 11:00 p.m. In addition, in the event that fewer than 13 valid 8-hour averages are available, a daily maximum 8-hour average O_3 concentration shall also be considered valid if it is greater than the level of the NAAQS. Hourly O_3 concentrations that have been approved under § 50.14 as having been affected by exceptional events shall be included when determining whether these criteria have been met.

(e) The primary and secondary O_3 design value statistic is the annual fourth-highest daily maximum 8-hour O_3 concentration, averaged over three years, expressed in parts per million. The fourth-highest daily maximum 8-hour O_3 concentration for each year shall be determined based only on days meeting the validity criteria in 3(d). The 3-year average shall be computed using the three most recent, consecutive years of ambient O_3 monitoring data. Design values shall be reported to three decimal places, with additional digits to the right of the third decimal place truncated.

4. Comparisons With the Primary and Secondary Ozone NAAQS

(a) The primary and secondary national ambient air quality standards for O_3 are met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration (*i.e.,* the design value) is less than or equal to (0.065–0.070) ppm.

(b) A design value greater than the level of the NAAQS is always considered to be valid. A design value less than or equal to the level of the NAAQS must meet minimum data completeness requirements in order to be considered valid. These requirements are met for a 3-year period at a site if valid daily maximum 8-hour average O_3 concentrations are available for at least 90% of the days within the O_3 monitoring season, on average, for the 3-year period, with a minimum of at least 75% of the days within the O_3 monitoring season in any one year.

(c) When computing whether the minimum data completeness requirements have been met, meteorological or ambient data may be sufficient to demonstrate that meteorological conditions on missing days were not conducive to concentrations above the level of the NAAQS. Missing days assumed less than the level of the NAAQS are counted for the purpose of meeting the minimum data completeness requirements, subject to the approval of the appropriate Regional Administrator.

(d) Comparisons with the primary and secondary O_3 NAAQS are demonstrated by examples 1 and 2 as follows:

Example 1: Site Meeting the Primary and Secondary O_3 NAAQS

Year	Percent valid days within O_3 monitoring season	1st highest daily max 8-hour O_3 (ppm)	2nd highest daily max 8-hour O_3 (ppm)	3rd highest daily max 8-hour O_3 (ppm)	4th highest daily max 8-hour O_3 (ppm)	5th highest daily max 8-hour O_3 (ppm)
2014	100	0.082	0.080	0.075	0.069	0.068
2015	96	0.074	0.073	0.065	0.062	0.060
2016	98	0.070	0.069	0.067	0.066	0.060
Average	98	.....	.....	.....	0.065	.....

As shown in Example 1, this site meets the primary and secondary O_3 NAAQS because the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations (*i.e.,* 0.065666 ppm, truncated to 0.065 ppm) is less than or equal to (0.065–0.070) ppm. The minimum data completeness requirements are also met because the average percent of days within the O_3 monitoring season with valid ambient monitoring data is greater than 90%, and no single year has less than 75% data completeness.

Example 2: Site Failing to Meet the Primary and Secondary O3 O_3 NAAQS

Year	Percent valid days within O_3 monitoring season	1st highest daily max 8-hour O_3 (ppm)	2nd highest daily max 8-hour O_3 (ppm)	3rd highest daily max 8-hour O_3 (ppm)	4th highest daily max 8-hour O_3 (ppm)	5th highest daily max 8-hour O_3 (ppm)
2014	96	0.085	0.080	0.079	0.074	0.072
2015	74	0.084	0.083	0.072	0.071	0.068
2016	98	0.083	0.081	0.081	0.075	0.074
Average	89	.....	.....	.....	0.073	.....

As shown in Example 2, this site fails to meet the primary and secondary O_3 NAAQS because the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentrations (*i.e.,* 0.073333 ppm, truncated to 0.073 ppm) is greater than (0.065–0.070) ppm, even though the annual data completeness is less than 75% in one year and the 3-year average data completeness is less than 90%.

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENATION PLANS

■ 6. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

Subpart I—Review of New Sources and Modifications

■ 7 Amend § 51.166 by adding paragraph (i)(11) to read as follows:

§ 51.166 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(11) The plan may provide that the requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for ozone in effect on [EFFECTIVE DATE OF FINAL RULE] if:

(i) The reviewing authority has determined a permit application subject to this section to be complete on or before [SIGNATURE DATE OF FINAL RULE]. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for ozone in effect at the time the reviewing authority determined the permit application to be complete; or

(ii) The reviewing authority has first published before [EFFECTIVE DATE OF FINAL RULE] a public notice of a preliminary determination or draft permit for the permit application subject to this section. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for ozone in effect at the time of first publication of a public notice of the preliminary determination or draft permit.

* * * * *

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 9. Amend § 52.21 by adding paragraph (i)(12) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(12) The requirements of paragraph (k)(1) of this section shall not apply to a stationary source or modification with respect to the national ambient air quality standards for ozone in effect on [EFFECTIVE DATE OF FINAL RULE] if:

(i) The Administrator has determined a permit application subject to this section to be complete on or before [SIGNATURE DATE OF FINAL RULE]. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for ozone in effect at the time the Administrator determined the permit application to be complete; or

(ii) The Administrator has first published before [EFFECTIVE DATE OF FINAL RULE] a public notice of a preliminary determination or draft permit subject to this section. Instead, the requirements in paragraph (k)(1) of this section shall apply with respect to the national ambient air quality standards for ozone in effect on the date the Administrator first published a public notice of a preliminary determination or draft permit.

* * * * *

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

■ 10. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

Subpart A—General Provisions

§ 53.9 [Amended]

■ 11. Amend § 53.9 by removing paragraph (i).

■ 12. Amend § 53.14 by revising paragraph (c) introductory text to read as follows:

§ 53.14 Modification of a reference or equivalent method.

* * * * *

(c) Within 90 calendar days after receiving a report under paragraph (a) of this section, the Administrator will take one or more of the following actions:

* * * * *

Subpart B—Procedures for Testing Performance Characteristics of Automated Methods for SO_2, CO, O_3, and NO_2

■ 13. Amend § 53.23 by revising paragraph (e)(1)(vi) to read as follows:

§ 53.23 Test procedures.

* * * * *

(e) * * *

(1) * * *

(vi) *Precision:* Variation about the mean of repeated measurements of the same pollutant concentration, denoted as the standard deviation expressed as a percentage of the upper range limits.[282]

* * * * *

■ 14. Revise Table B–1 to Subpart B of Part 53 to read as follows:

TABLE B–1 TO SUBPART B OF PART 53—PERFORMANCE LIMIT SPECIFICATIONS FOR AUTOMATED METHODS

Performance parameter	Units [1]	SO_2		O_3		CO		NO_2 (Std. range)	Definitions and test procedures
		Std. range [3]	Lower range [2,3]	Std. range [3]	Lower range [2,3]	Std. range [3]	Lower range [2,3]		
1. Range	ppm	0–0.5	<0.5	0–0.5	<0.5	0–50	<50	0–0.5	Sec. 53.23(a).
2. Noise	ppm	0.001	0.0005	0.001	0.0005	0.2	0.1	0.005	Sec. 53.23(b).
3. Lower detectable limit	ppm	0.002	0.001	0.003	0.001	0.4	0.2	0.010	Sec. 53.23(c).
4. Interference equivalent									
Each interferent	ppm	±0.005	4±0.005	±0.005	±0.005	±1.0	±0.5	±0.02	Sec. 53.23(d).
Total, all interferents	ppm	.....	.....	.....	.....	.....	.....	0.04	Sec. 53.23(d).
5. Zero drift, 12 and 24 hour	ppm	±0.004	±0.002	±0.004	±0.002	±0.5	±0.3	±0.02	Sec. 53.23(e).
6. Span drift, 24 hour									

[282] NO_2 precision in Table B–1 is also changed to percent to agree with the calculation specified in 53.23(e)(10)(vi).

TABLE B–1 TO SUBPART B OF PART 53—PERFORMANCE LIMIT SPECIFICATIONS FOR AUTOMATED METHODS—Continued

Performance parameter	Units [1]	SO_2		O_3		CO		NO_2 (Std. range)	Definitions and test procedures
		Std. range [3]	Lower range [2,3]	Std. range [3]	Lower range [2,3]	Std. range [3]	Lower range [2,3]		
20% of upper range limit	Percent							±20.0	Sec. 53.23(e).
80% of upper range limit	Percent	±3.0	±3.0	±3.0	±3.0	±2.0	±2.0	±5.0	Sec. 53.23(e).
7. Lag time	Minutes	2	2	2	2	2.0	2.0	20	Sec. 53.23(e).
8. Rise time	Minutes	2	2	2	2	2.0	2.0	15	Sec. 53.23(e).
9. Fall time	Minutes	2	2	2	2	2.0	2.0	15	Sec. 53.23(e).
10. Precision									
20% of upper range limit									Sec. 53.23(e).
	Percent [5]	2	2	2	2	1.0	1.0	4	Sec. 53.23(e).
									Sec. 53.23(e).
80% of upper range limit	Percent [5]	2	2	2	2	1.0	1.0	6	Sec. 53.23(e).

[1] To convert from parts per million (ppm) to μg/m³ at 25 °C and 760 mm Hg, multiply by M/0.02447, where M is the molecular weight of the gas. Percent means percent of the upper measurement range limit.

[2] Tests for interference equivalent and lag time do not need to be repeated for any lower range provided the test for the standard range shows that the lower range specification (if applicable) is met for each of these test parameters.

[3] For candidate analyzers having automatic or adaptive time constants or smoothing filters, describe their functional nature, and describe and conduct suitable tests to demonstrate their function aspects and verify that performances for calibration, noise, lag, rise, fall times, and precision are within specifications under all applicable conditions. For candidate analyzers with operator-selectable time constants or smoothing filters, conduct calibration, noise, lag, rise, fall times, and precision tests at the highest and lowest settings that are to be included in the FRM or FEM designation.

[4] For nitric oxide interference for the SO_2 UVF method, interference equivalent is ±0.0003 ppm for the lower range.

[5] Standard deviation expressed as percent of the URL.

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Table B-3 to Subpart B of Part 53—Interferent Test Concentration,[1] Parts per Million

Pollutant	Analyzer type	Hydrochloric acid	Ammonia	Hydrogen sulfide	Sulfur dioxide	Nitrogen dioxide	Nitric oxide	Carbon dioxide	Ethylene	Ozone	m-Xylene	Water vapor	Carbon monoxide	Methane	Ethane	Naphthalene
SO_2	Ultraviolet fluorescence			[5]0.1	[4] 0.14	0.5	0.5			0.5	0.2	20,000				0.05
SO_2	Flame photometric			0.01	[4] 0.14			750				[3] 20,000	50			
SO_2	Gas chromatography			0.1	[4] 0.14			750				[3] 20,000	50			
SO_2	Spectrophotometric-wet chemical (pararosanaline)	0.2	0.1	0.1	[4] 0.14	0.5		750		0.5						
SO_2	Electrochemical	0.2	0.1	0.1	[4] 0.14	0.5	0.5		0.2	0.5		[3] 20,000				
SO_2	Conductivity	0.2	0.1		[4] 0.14	0.5		750								
SO_2	Spectrophotometric-gas phase, including DOAS				[4] 0.14	0.5				0.5	0.2					
O_3	Ethylene chemiluminescene			[3] 0.1				750		0.08		[3] 20,000				
O_3	NO-chemiluminescene			[3] 0.1		0.5		750		0.08		20,000				
O_3	Electrochemical		[3] 0.1		0.5	0.5				0.08						

O_3	Spectrophotometric-wet chemical (potassium iodide)		[3] 0.1		0.5	0.5	0.5			0.08					
O_3	Spectrophotometric-gas phase, including ultraviolet absorption and DOAS				0.5	0.5	0.5			0.08	0.02	20,000			
CO	Non-dispersive Infrared							750				20,000	[4] 10		
CO	Gas chromatography with flame ionization detector											20,000	[4] 10		0.5
CO	Electrochemical						0.5		0.2			20,000	[4] 10		
CO	Catalytic combustion-thermal detection		0.1					750	0.2			20,000	[4] 10	5.0	0.5
CO	IR fluorescence							750				20,000	[4] 10		0.5
CO	Mercury replacement-UV photometric								0.2				[4] 10		0.5
NO_2	Chemiluminescent		[3] 0.1		0.5	[4] 0.1	0.5					20,000			
NO_2	Spectrophotometric-wet chemical (azo-dyereaction)				0.5	[4] 0.1	0.5	750		0.5					

NO_2	Electrochemical	0.2	[3] 0.1		0.5	[4] 0.1	0.5	750		0.5		20,000	50			
NO_2	Spectrophotometric-gas phase		[3] 0.1		0.5	[4] 0.1	0.5			0.5		20,000	50			

1. Concentrations of interferents listed must be prepared and controlled to ±10 percent of the stated value.
2. Analyzer types not listed will be considered by the Administrator as special cases.
3. Do not mix with the pollutant.
4. Concentration of pollutant used for test. These pollutant concentrations must be prepared to ±10 percent of the stated value.
5. If candidate method utilizes an elevated-temperature scrubber for removal of aromatic hydrocarbons, perform this interference test.
6. If naphthalene test concentration cannot be accurately quantified, remove the scrubber, use a test concentration that causes a full scale response, reattach the scrubber, and evaluate response for interference.

■ 15. Revise table B–3 to subpart B of part 53 to read as follows:

■ 16. Amend appendix A to subpart B of part 53 by revising "Figure B–5" to read as follows:

* * * * *

Appendix A to Subpart B of Part 53—Optional Forms for Reporting Test Results

CALCULATION OF ZERO DRIFT, SPAN DRIFT, AND PRECISION

Applicant_____ Date_____

Analyzer_____ Pollutant_____

TEST PARAMETERS		CALCULATIONS	TEST DAY (n)														
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
ZERO DRIFT	12 HOUR	$12ZD = C_{max} - C_{min}$															
	24 HOUR	$Z = (L_1 + L_2)/2$															
		$24ZD = Z_n - Z_{n-1}$															
		$24ZD = Z'_n - Z'_{n-1}$															
SPAN DRIFT	24 HOUR	$S_n = \frac{1}{6}\sum_{i=7}^{12} P_i$															
		$SD_n = \frac{S_n - S_{n-1}}{S_{n-1}} \times 100\%$															
		$SD_n = \frac{S_n - S'_{n-1}}{S'_{n-1}} \times 100\%$															
PREC-ISION	20% URL (P_{20})	P_{20} = % STANDARD DEVIATION OF ($P_1 \ldots P_6$)															
	80% URL (P_{80})	P_{80} = % STANDARD DEVIATION OF ($P_7 \ldots P_{12}$)															

Figure B-5. Form for calculating zero drift, span drift, and precision (§ 53.23(e)).

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* * * * *

Subpart C—Procedures for Determining Comparability Between Candidate Methods and Reference Methods

■ 17. Amend § 53.32 by revising paragraph (g)(1)(iii) to read as follows:

§ 53.32 Test procedures for methods for SO_2, CO, O_3, and NO_2.

* * * * *

(g) * * *

(1) * * *

(iii) The measurements shall be made in the sequence specified in table C–2 of this subpart.

* * * * *

Figure E–2 to Subpart E of Part 53 [Removed]

■ 18. Amend subpart E by removing figure E–2 to subpart E of part 53.

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

■ 19. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7405, 7410, 7414, 7601, 7611, 7614, and 7619.

Subpart B—Monitoring Network

■ 20. Amend § 58.10 by adding paragraphs (a)(10) and (11) to read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment

(a) * * *

(10) The annual monitoring network plan shall provide for the required O_3 sites to be operating on the first day of the applicable required O_3 monitoring season in effect on January 1, 2017 as listed in Table D–3 of appendix D of this part.

(11) The annual monitoring network plan shall include the Enhanced Monitoring Plan (EMP) for areas designated as O_3 nonattainment, as required under 40 CFR part 58 Appendix D, section 5(f) beginning with the annual monitoring plans due on July 1, 2016.

* * * * *

■ 21. Amend § 58.13 by adding paragraphs (g) and (h) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(g) The O_3 monitors required under appendix D, section 4.1 of this part must operate on the first day of the applicable required O_3 monitoring season in effect January 1, 2017.

(h) The Photochemical Assessment Monitoring sites required under 40 CFR part 58 Appendix D, section 5(a) must be physically established and operating under all of the requirements of this part, including the requirements of appendix A, C, D, and E of this part, no later than June 1, 2017, or two years following designation as O_3 nonattainment.

Subpart F—Air Quality Index Reporting

■ 22. Amend § 58.50 by revising paragraph (c) to read as follows:

§ 58.50 Index reporting.

* * * * *

(c) The population of a metropolitan statistical area for purposes of index reporting is the latest available U.S. census population.

Subpart G—Federal Monitoring

■ 23. Amend Appendix D to Part 58, under section 4, by revising section 4.1(i) and Table D–3 to Appendix D of part 58 and by revising section 5 to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4. Pollutant-Specific Design Criteria for SLAMS Sites

4.1 Ozone (O_3) Design Criteria. * * *

(i) Since O_3 levels decrease significantly in the colder parts of the year in many areas, O_3 is required to be monitored at SLAMS monitoring sites only during the ''ozone season'' as described below in Table D–3 of this appendix. These ozone seasons are also identified in the AQS files on a state-by-state basis. Deviations from the O_3 monitoring season must be approved by the EPA Regional Administrator. These requests will be reviewed by Regional Administrators taking into consideration, at a minimum, the frequency of out-of-season O_3 NAAQS exceedances, as well as occurrences of the Moderate air quality index level and regional consistency. Any deviations based on the Regional Administrator's waiver of requirements must be described in the annual monitoring network plan and updated in AQS. Changes to the O_3 monitoring season requirements in Table D–3 revoke any previously approved Regional Administrator waivers for affected states. Requests for monitoring season waivers must be accompanied by relevant supporting information. Information on how to analyze O_3 data to support a change to the O_3 season in support of the 8-hour standard for a specific state can be found in reference 8 to this appendix. O_3 monitors at NCore stations are required to be operated year-round (January to December).

TABLE D–3 [1] TO APPENDIX D OF PART 58—OZONE MONITORING SEASON BY STATE

State	Begin month	End month
Alabama	March	October.
Alaska	April	October.
Arizona	January	December.
Arkansas	March	November.
California	January	December.
Colorado	January	December.
Connecticut	March	September.
Delaware	March	October.
District of Columbia.	March	October.
Florida	January	December.
Georgia	March	October.
Hawaii	January	December.
Idaho	April	September.
Illinois	March	October.
Indiana	March	October.
Iowa	March	October.
Kansas	March	October.
Kentucky	March	October.
Louisiana (Northern) AQCR 019,022.	March	October.
Louisiana (Southern) AQCR 106.	January	December.
Maine	April	September.
Maryland	March	October.
Massachusetts	March	September.
Michigan	March	October.
Minnesota	March	October.
Mississippi	March	October.
Missouri	March	October.
Montana	April	September.
Nebraska	March	October.
Nevada	January	December.
New Hampshire	March	September.
New Jersey	March	October.
New Mexico	January	December.
New York	March	October.
North Carolina	March	October.
North Dakota	March	September.
Ohio	March	October.
Oklahoma	March	November.
Oregon	May	September.
Pennsylvania	March	October.
Puerto Rico	January	December.
Rhode Island	March	September.
South Carolina	March	October.
South Dakota	March	October.
Tennessee	March	October.
Texas (Northern) AQCR. 022, 210, 211, 212, 215, 217, 218.	March	November.
Texas (Southern) AQCR. 106, 153, 213, 214, 216.	January	December.
Utah	January	December.
Vermont	April	September.
Virginia	March	October.
Washington	May	September.
West Virginia	March	October.
Wisconsin	March	October 15.
Wyoming	January	September.
American Samoa.	January	December.
Guam	January	December.

TABLE D–3 [1] TO APPENDIX D OF PART 58—OZONE MONITORING SEASON BY STATE—Continued

State	Begin month	End month
Virgin Islands ...	January	December.

[1] The required O_3 monitoring season for NCore stations is January through December.

* * * * *

5. Network Design for Photochemical Assessment Monitoring Stations (PAMS) and Enhanced Ozone Monitoring

(a) State and local monitoring agencies are required to collect and report the following PAMS measurements at each NCore site required under paragraph 3(a) of this appendix located in an area designated as nonattainment for O_3.

(b) PAMS measurements include:

(1) Hourly averaged speciated volatile organic compounds (VOCs),

(2) 8 3-hour averaged carbonyls daily,

(3) Hourly averaged O_3,

(4) Hourly averaged nitrogen oxide (NO), nitrogen dioxide (NO_2), and total reactive nitrogen (NO_y),

(5) Hourly averaged 3 meter ambient temperature,

(6) Hourly vector-averaged 10 meter wind direction,

(7) Hourly averaged 10 meter wind speed,

(8) Hourly average atmospheric pressure,

(9) Hourly averaged relative humidity, and

(10) Hourly averaged mixing-height.

(c) The EPA Regional Administrator may grant a waiver to allow the collection of required PAMS measurements at an alternative location where the monitoring agency can demonstrate that the alternative location will provide representative data useful for regional or national scale modeling and the tracking of trends in O_3 precursors.

(d) The EPA Regional Administrator may also grant a waiver to allow representative meteorological data from nearby monitoring stations to be used to meet the requirements to collect temperature, wind direction, wind speed, atmospheric pressure, relative humidity, or hourly averaged mixing height where the monitoring agency can demonstrate the data is collected in a manner consistent with EPA quality requirements for these measurements.

(e) At a minimum, the monitoring agency shall collect the required PAMS measurements during the months of June, July, and August.

(f) States with O_3 nonattainment areas are required to develop and implement an Enhanced Monitoring Plan (EMP) detailing enhanced O_3 and O_3 precursor monitoring activities to be performed which is subject to review and approval by the EPA Regional Administrator. The EMP will include monitoring activities deemed important to understanding the O_3 problems in the state. Such activities may include, but are not limited to, the following:

(1) Additional O_3 monitors beyond the minimally required under paragraph 4.1 of this appendix,

(2) Additional NO_X or NO_y monitors beyond those required under 4.3 of this appendix,

(3) Additional speciated VOC measurements including data gathered during different periods other than required under paragraph 5(e) of this appendix, or locations other than those required under paragraph 5(a) of this appendix, and

(4) Enhanced upper air measurements of meteorology or pollution concentrations.

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Part III

The President

Proclamation 9220—Bill of Rights Day, 2014

Federal Register
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Presidential Documents

Title 3—

The President

Proclamation 9220 of December 12, 2014

Bill of Rights Day, 2014

By the President of the United States of America

A Proclamation

For more than two centuries, our Nation has been shaped by courageous women and men who have dared to raise their voices and work to safeguard the blessings of liberty and justice. In the face of tyranny, early patriots stood up against an empire and proclaimed the independence of a new Nation, declaring that we are all created equal, endowed by our Creator with unalienable rights. To secure these rights, they fought a war and enshrined these truths into our Constitution. The product of a fierce debate and great compromise, our founding charter was a remarkable yet imperfect document. It provided the foundation for a society built on freedom and democracy, but essential questions—including those of race and gender—were left unresolved. Yet before it was fully ratified, our Founding Fathers began working to refine its text, an early milestone in our unending journey to form a more perfect Union.

Ratified on December 15, 1791, the Bill of Rights secured our most fundamental freedoms. These first 10 Constitutional Amendments protect our rights to protest, practice our faiths, and hold our Government accountable. They guarantee justice under the law, allow for the dissemination of new ideas, and create the opportunity for those left out of our charter to fight to expand its promise. In times of war and peace, and through waves of depression and prosperity, these tenets have not only endured, but they have strengthened our Nation and served as an example to all who seek freedom, fairness, equality, and dignity around the world.

On the anniversary of the Bill of Rights, we reflect on the blessings of freedom we enjoy today, and we are reminded that our work to foster a more free, more fair, and more just society is never truly done. Guided by these sacred principles, we continue striving to make our country a place where our daughters' voices are valued just as much as our sons'; where due process of law is afforded to all people, regardless of skin color; and where the individual liberties that we cherish empower every American to pursue their dreams and achieve their own full measure of happiness.

Our fidelity to these timeless ideals binds us together as a Nation. As we celebrate Bill of Rights Day, let us recommit to the values that define us as a people and continue our work to broaden democracy's reach by strengthening the freedoms with which we have been endowed.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim December 15, 2014, as Bill of Rights Day. I call upon the people of the United States to mark this observance with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of December, in the year of our Lord two thousand fourteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

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